California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AG
DEPARTMENT OF CONSUMER AF
ARNOLD SCHWARZENEGGER, GOVE

Contact Person: Patricia Harris
(916) 445-5014

ENFORCEMENT COMMITTEE MEETING

June 23, 2004
9:30 a.m. – 12:30 p.m.

Department of Consumer Affairs
Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Members of the board who are not on the committee may attend and comment during the meeting.

AGENDA

CALL TO ORDER **9:30 a.m.**

A. Discussion Regarding the Reimportation of Prescription Drugs from Canada

B. Disclosure of Citation and Fines to the Public

C. Request from Rite Aid Corporation to Accept Biometric Fingerprint Recognition Technology as a Substitute for Pharmacist Signature on the Prescription Label

D. Evaluation of the Implementation of Quality Assurance Program

E. Changes to the Retired Status of a Physician – No Longer Can Engage in the Practice of Medicine

F. Discussion Regarding the Implementation of SB 151 (Chapter 406, Statutes of 2003) – New Requirements for Controlled Substance Prescriptions and the Elimination of the Triplicate Questions and Answers

G. Update on the Implementation of Legislation Regarding Wholesalers – Introduction of SB 1307 (Senator Figueroa)

H. Report on the Implementation of the Citation and Fine Program for 2002/03 and 2003/04

I. Adjournment **12:30 p.m.**

Committee materials will be available on the board's website by June 16, 2004

Agenda Item A

NABP 100 YEARS
1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

VIA FAX

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
STATE ATTORNEYS GENERAL

FROM: Mary A. Dickson, Associate Executive Director

DATE: June 2, 2004

RE: Importation Enforcement Workshop & Task Force Meeting

Attached is the agenda for the Importation Enforcement Workshop & Task Force Meeting. We are confirming speakers and making final arrangements for this meeting. As further information becomes available, we will forward it to you.

Travel Arrangements

NABP has engaged the services of Options Travel, located in Des Plaines, Illinois to handle the airline reservations for all Association meetings. **Association policy requires that all NABP-related travel arrangements be made through our designated agent.** We ask that you plan to arrive in Arlington on the evening of Monday, June 21, 2004, and plan your departure for anytime after 2 PM Wednesday, June 23, 2004. When you are ready to make your airline reservations to attend the meeting, please contact:

Options Travel
1-800/544-8785
Meeting code: 1105
(Please mention the meeting code when making your flight arrangements.)

Please make your airline reservation as soon as possible. As we approach the meeting date, a delay in this regard could result in a higher airfare.

National Association of Boards of Pharmacy
700 Busse Highway • Park Ridge, IL 60068 • Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

All Options Travel agents are aware that you will be contacting them for airline reservations and can help you book your tickets. Simply let them know that you will be participating in the Importation Enforcement Workshop & Task Force Meeting when you make your reservations.

Hotel Reservation Form: Enclosed you will find a hotel reservation form for the Ritz Carlton Pentagon City in Arlington, Virginia. Please complete the requested form information, and fax or e-mail the form to the attention of Leslie Mahaffey, NABP's meeting planning manager, at fax number: 847/698-0124; or e-mail address: lmahaffey@nabp.net as soon as possible. NABP will make your hotel reservations.

We have also attached an expense form for you to send back to us with your expenses, if you are applying for the travel grant.

If you are interested in attending this workshop, please contact Chris Siwik at csiwik@nabp.net or by phone at 847/698-2612, by June 4, 2004.

Attachments: Agenda
Hotel Reservation Form
Expense Report

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Chris Siwik, Administrative Assistant

Importation Enforcement Workshop and Task Force Meeting
Ritz Carlton Pentagon City, Arlington, VA
June 22-23, 2004

Agenda

The Workshop on Importation Enforcement will be held from 8:30 AM to 1 PM on Tuesday, June 22, 2004, and 8:30 AM to 1 PM on Wednesday, June 23, 2004. A continental breakfast and lunch will be served on Tuesday and Wednesday. Following the luncheon on Tuesday, the task force meeting will begin.

Task force members only will meet from 1- 5 PM on Tuesday. The meeting on Wednesday, June 23, 2004, will be open to all task force members and guests.

Tuesday, June 22, 2004

8 – 8:30 AM	Breakfast
8:30 – 8:45 AM	Review of Confidentiality Agreement
8:45 – 9 AM	Welcome and Introduction
9 AM – Noon	Guest Instruction Topics (approximately 45 minutes each) FDA: Actions taken to date; violations found; evidence of public safety dangers; Boards: Case Studies: Successful prosecutions of importation cases; violations found; identify successful strategies; State Attorneys General: Enforcement actions; violations found; prosecution strategies
Noon – 1 PM	Lunch

Task Force Meeting (for task force members only)

1 – 1:30 PM	Review of NABP Mission Statement
	Review of Agenda
	Review of the Task Force Charge
	Overview of Task Force Materials
1:30 – 5 PM	Review of Presentations
	Discussion:
	Examine present regulatory structure of boards of pharmacy and the states and how that regulatory structure was impacted by importation issue

Wednesday, June 23, 2004

8 – 8:30 AM	Continental Breakfast
8:30 – 9 AM	Recap of Tuesday's discussion
9 AM – Noon	Potential impact of future public policy issues such as importation and globalization
	Draft template (guidelines) for prosecution of illegal importation cases; individualized for each state
	Strategic Planning Outline Phase I (addresses changing regulatory landscape and evolving globalization of society)
	Next Steps
Noon – 1 PM	Lunch
1 – 2 PM	Media Event (coordinated by Pfizer; at National press club); participants include Carmen Catizone, one attorney general, National Association of Pharmacy Regulatory Authorities (NAPRA) representative, board of pharmacy representative

NABP 100 YEARS
1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director MAD

DATE: May 21, 2004

RE: Actions Against Organizations Facilitating Importation of Canadian Medications

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Attached is an updated Excel spreadsheet listing the most recent information that NABP has obtained from the boards of pharmacy and media concerning informal and formal actions that state, federal, and other regulatory agencies have initiated against storefronts, pharmacies, and other groups and individuals who facilitate or otherwise assist in the illegal importation of unapproved prescription medications from Canada.

Please feel free to continue providing us with additional information as it becomes available so that we can add the data to our spreadsheet and periodically provide the boards of pharmacy with updates.

Thank you for your assistance in compiling this table.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Jim Weiss, Information Technology and Services Director
Courtney Nashan, Communications and Services Senior Manager
Moira Gibbons, ELTP/VIPPS Manager
Charisse Johnson, Professional Affairs Manager

National Association of Boards of Pharmacy
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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
AK	**7/1/03** - No actions have been initiated to date.		
AL	**3/20/03** - AL BOP filed a complaint against **Discount Drugs of Canada (DDC)** and its owner/operators, Timothy Morton & Steve Reese, in the Circuit Court of Jefferson County, seeking a temporary restraining order (TRO) as well as preliminary & permanent injunctive relief, due to allegations that it is, among other things, engaging in the unauthorized practice of pharmacy in AL. The TRO was granted by the court the same day of the filing, and the Board immediately enforced the order, shutting down DDC. **3/31/03** - Circuit Court of Jefferson County issued an order extending a previously entered temporary restraining order (TRO) against DDC, until further court order. **6/30/03** - Board's request was granted and a circuit court issued a temporary restraining order against **Canadian Discount Drugs**. A hearing on the Board's request for a preliminary injunction is scheduled for July 8, 2003.	**6/03 - FDA** issued warning letter to staff of **CanadianDiscountDrugs** and **Ameri-Can Global Pharmaceutical Supply, Inc**, in Ozark, AL, which assists US consumers in obtaining prescription drugs from Canada, specifically **Total Care Pharmacy** in Calgary, Alberta, CAN.	
AR	**3/03** - BOP issued a warning letter to **Rx Depot (www.therxDepot.com)**, Lowell, AR, a company that facilitates US consumers obtaining Canadian prescription medications.	**3/21/03 - (Rx Depot/www.therxDepot.com)** - the **FDA** issued a warning letter to the company, located in Lowell, AR, notifying the firm that the agency considered the firm's operations to be illegal and a risk to public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. FDA is also acting in conjunction with AR BOP action. **4/10/03** - the **Manitoba Pharmaceutical Association** in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of **Northgate Clinic Pharmacy,** 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The warning letter states that Northgate Clinic Pharmacy must immediately cease business agreements with Rx Depot in any state, that Rx Depot is operating in AR in violation of the state law, and that it has been given direction from the State Board of Pharmacy to cease its operation.	

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AZ	**2002-2003** – Seven (7) Canadian pharmacies applied for nonresident pharmacy permits. The Board requested information on how they would comply with FDA regulations on importation. None of the applicants has responded; their applications have been deemed incomplete. **5/9/03** - AZ BOP issued a letter to the AZ Better Business Bureau asking it to warn consumers about the risks of purchasing prescription drugs illegally from Canada and other foreign countries. The letter cited the sentencing of Rory Dannenberg, operator of **Value Prescriptions** located in Phoenix, AZ, for an unrelated felony conviction. Dannenberg is one of several illegal Canadian prescription service operators being investigated by the Board for offering prescription drugs for sale without a pharmacy permit and without a licensed RPh in place.		
CA	**7/1/03** - No actions have been initiated to date. **10/20/03** - Nothing to report.	**8/03 - FDA** issued a written opinion in response to a 7/03 letter from the CA Attorney General inquiring about the importation of prescription drugs from Canada into the state of California. FDA notifies the CA AG about the legal and safety issues concerning the importation of prescription drugs.	**2/04 - CA S1144** - A bill introduced in the California Senate would authorize the Department of General Services to negotiate contracts with Canadian sources for the purchase of prescription drugs, in addition to existing sources such as prescription drug manufacturers, wholesalers and suppliers. **2/04: AB 1957 (Frommer D-Los Angeles)** calls for the state to buy Canadian meds, and proposes to have the **CA State Board of Pharmacy** establish a consumer Web site to help patients buy drugs from certified Canadian drugstores.

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CO	**10/03** - Board is reviewing its laws and considering amendments to strengthen the language.	**2003-2003** - AG is reviewing whether to take action against individuals that facilitate foreign business. **11/03 (article from www.ajc.com)** - The 10th US Circuit Court of Appeals in Denver denied a request from **Rx Depot**, which asked that its 85 stores be allowed to continue operating until a ruling on its appeal. **2/04** - (Rocky Mountain News) - CO regulators urged the FDA and CO attorney general to investigate an Englewood retailer that helps consumers buy prescription drugs from Canada. The Dept of Regulatory Agencies said 2-week-old **Canada Drug Service** is "flouting federal law" and misleading consumers in its radio ads. **5/6/04**: **Rx Depot** filed a petition in federal court requesting that the ban on its operations be lifted. **Rx Depot Inc.** asked the Denver-based 10th US Federal Circuit Court of Appeals to hear arguments because of the "significant public policy implications" for the elderly and poor.	
CT	**7/2/03** - No actions have been initiated to date.		
DC			
DE	**1/8/03** - At its January meeting, the Board voiced its concerns and strong opposition to the importation of medications from Canada. The Board formalized its concerns in a letter encouraging NABP to oppose this activity.		
FL	**8/02** – Board denied a nonresident pharmacy license to a Canadian pharmacy: statutes require that pharmacy be located in a US state. **12/02** – FL Board attorney issues legal opinion stating businesses that assist people in importing prescription medications should be treated like pharmacies because they lead to prescriptions being dispensed. **1/04** - NABP staff discovered that the Florida Board issued a non-resident pharmacy license #PH17987 to Canadian pharmacy **Adv-Care/Adv-Care.com** based in Markham, Ontario, Canada. **2/04** - A Board representative indicated that licenses were mistakenly issued to two Canadian pharmacies, and that the Department was going through procedures to revoke/invalidate the licenses. In fact, the Board may be reviewing the **Adv-Care** license matter at its upcoming meeting.		

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GA		**6/03 - FDA** issued a warning letter to president/CEO of **CanadianDiscountDrugs** in Peachtree, GA, a business that assists US consumers in obtaining prescription drugs from Canada, specifically **Total Care Pharmacy** in Calgary, Alberta, CAN.	
GU			
HI	**6/03** - No actions initiated to date. **10/03** - There are 2 pending cases currently under investigation - no other information is available at this time.	**6/03** - Pending.	
IA	**6/03** - Board sent a C&D letter to **Nuway Drug**.		
ID			
IL	**Early 2003** - Board inspectors initiated investigations into several storefronts.		
IN	**6/03** - Board has filed complaints with the Attorney General of IN. **9/8/03** - IN BOP requested that the AG file an injunction in Marion County Circuit Court against **Rx Depot, Inc** of 1647 N Shadeland Ave, Indianapolis, IN 46219 for violation of I.C. 25-26-13.		
KS			
KY			
LA	**9/02** - Cease and Desist Notification sent to **FNC Canadian Discount Medication** of Monroe, LA. **3/19/03** - Cease and Desist Notification sent to **Prescription Referral Services** of Monroe, LA. **9/26/03 - NorthlandMeds Pharmacy**, Winnipeg MB, CAN; **Total Care Pharmacy**, Calgary, AB, CAN; **American Drug Club**, Winnipeg, MB CAN; **American Medical Services LLC**, Gretna, LA; **Native American Rx**, Irving, NY; and **Southern Pharmacy Services**, Baton Rouge, LA. **10/8/03 - NorthcareDrugs.com** (aka Northcare), Winnipeg MB, CAN. **10/13/03 - Canada Discount Rx**, Winnipeg MB, CAN. **11/8/03 - NorthCareDrugs.com** refuses to obey a C&D order from the Board. **11/17/03** - C&D notice issued to **Access Canada Rx**. Since the issuance of the C&D order, the company has ceased operations in the state of LA.		

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LA	**3/22/04** - C&D notice issued to **Glenway Pharmacy**, 2213 Henderson Hwy, East St. Paul, Manitoba Canada R2E OB8 **3/22/04** - C&D notice issued to **Rx Metro**, 1308 W Thomas St, Hammond, IN 70401		
MA	**7/03** - Board has been closely monitoring the issue and has been providing info to the Office of the Attorney General.		**3/04** - Under a proposed bill, the state would be required to seek federal permission to help citizens buy drugs from Canada. If granted, Massachusetts would then set up a Web site listing Canadian Internet Pharmacies.
MD	**10/27/03** - BOP intends to send out about a half-dozen warning letters to storefront operations in its state in the coming weeks.		
ME			
MI			
MN	**7/2/03** - No actions initiated to date.		
MO	**7/2/03** - No actions initiated to date.		
MS	**7/2/03** - No actions initiated to date.		
MT	**3/03** – Board issued an official complaint against **RealFast Drug Store**, known as **RF Drugstore** (**www.realfastdrugstore.com**), located in Manitoba, CAN. **RF Drugstore** has entered into an arrangement with **Club Medz**, a storefront located in Great Falls, MT. Board also intends to take **Club Medz** to court within a month if it does not comply with the Board's order to cease and desist, and have been working with the FDA in hopes of obtaining the involvement as well. **4/03** – Board investigated **Club Medz**, issued a subpoena, and **Club Medz** ceased operations at the end of the business day on 4/11/03. Board had charged that the lay people manning the storefront were engaged in the unlicensed practice of pharmacy and that they were aiding and abetting an illegal act. **4/03** - Board filed a complaint with the **Manitoba Pharmaceutical Association** against **RealFast Drugstore (aka RF Drugstore)**. The matter is still under MPA's consideration.	**12/03** - Judge lifts injunction against Billings' **Rx Depot** Store. Judge Jeffrey Sherlock in Helena dissolved the temporary court Order against **Rx Depot** in August by the MT Board of Pharmacy, saying proper notice of a hearing on the injunction was not given.	

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MT	**Spring '03** - Several C&D letters have been sent to Canadian mail order pharmacies. **5/03** - Denied an out-of-state mail service pharmacy license to Canadian pharmacy on grounds that the Board is unable to license an entity to perform an illegal act. **5/03** - Contacted both a RPh and a layperson seeking to open storefront operations, counseling the RPh not to aid and abet illegal activity or face disciplinary action. The layperson was told that the Board would consider her to be engaged in the unlicensed practice of pharmacy and aiding and abetting an illegal act. So far, neither operation has begun. **6/03** - Began action against a new **Rx Depot** in Billings, MT, and will follow the same rationale as previously used in the **Club Medz** case. Informed the FDA of the situation via phone.		
MT	**7/30/03** - Board filed a petition for injunctive relief against **Sandra S. Kennedy d/b/a Rx Depot** based upon allegations of aiding and abetting the unlawful practice of pharmacy in violation of Montana law. **8/5/03** - MT Pharmacy Board's petition for a preliminary injunction was granted. **Sandra S. Kennedy d/b/a Rx Depot** was ordered to cease engaging in any type of prescription service involving advertising for, solicitation of, and transfer of prescription drug orders from consumers/patients, until further order of court. A hearing is scheduled for **11/20/03**. **10/03** - The board is preparing to file a complaint with the **Manitoba College of Pharmacists** against **CanadaDrugMart.com**, Manitoba license #32386. From now on, MT BOP will file a board complaint with Canadian authorities against any Canadian pharmacy advertising its services within the state.	**7/03 - FDA** sent a letter in support of Montana's actions case **Rx Depot**. **9/03 - Montana Pharmacy Association** offered to file an amicus brief on behalf of the Montana Board of Pharmacy, in the Board's case against **Rx Depot**.	

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NC	**6/11/03** - the NC BOP announced the issuance of Cease & Desist Orders for five businesses that are forwarding prescriptions to Canada to be filled and returned to the US. Orders were sent to: **Discount Drugs of Canada**, Gastonia, NC; **Canada Drug Outlet Inc**, Concord, NC; **Rx Price is Right, Inc**, Winston-Salem, NC; **Canada Drugs**, Asheboro, NC; and **Prescription Care of NC**, Banner Elk, NC. **7/14/03** - Per Carlson Carmichael, lawyer for the NC BOP, as of mid-June 2003, they have sent C&Ds to 6 locations in NC that are storefront-type operations. **10/15/03** - Board filed suit against five (5) storefronts in NC and is seeking preliminary injunctions. The hearings are to be held on **11/20/03**. **11/03** - NC judge ordered **Canada Outlet** to show that it complies with state law. After 10 days, the judge will determine whether or not to grant a preliminary injunction. **11/03 - Prescription Care of North Carolina** signed a consent Order. **11/03 - Discount Drugs of Canada** is no longer operating.	**7/1/03 - FDA** issued a letter supporting the Board's efforts to stop businesses that forward prescriptions to Canada to be filled by Canadian pharmacies for US consumers, and the FDA offered its assistance in the Board's efforts to stop such businesses. **4/04** - North Carolina's Caldwell County links employees with Canadian pharmacies. The FDA and NC BOP have sent the county letters of objection.	
NC	**1/9/04** - David Work of the NC BOP called NABP and stated the Board had just won an injunction against a Canadian storefront, located in Concord. **2/04** - The NC Board of Pharmacy is trying to shutter the last storefront Canadian prescription service in the Charlotte area. The board ordered **"Canada Connection"** to stop doing business in NC and helping people place orders with Canadian pharmacies. **4/04** - The NC Board of Pharmacy wrote to the **Manitoba Pharmaceutical Association** about **Redwood Drugs** of Winnipeg. The letter states that **Redwood Drugs**, **www.redwooddrugs.ca**, is soliciting residents of North Carolina, but **Redwood Pharmacy** does not have an out-of-state pharmacy permit, which is required according to North Carolina law.		

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ND	**Fall 2002** – BOP has sent numerous cease and desist orders to Canadian and other international pharmacies that ship into ND. **9/5/03** - ND BOP sent a C&D letter to: **Arnel A. Inocando, Redwood Drugs,** Winnipeg, Manitoba, CAN for: 1) offering to ship prescription medications to ND; 2) offering to pay physicians for referral of prescription business. **9/9/03** - C&D letter sent to **David King** of **Canada Direct Pharmacy** in Calgary, Alberta, CAN, for offering a financial and business referral arrangement between one health care provider and another. **10/17/03** - A C&D letter was sent to **Canada Direct Pharmacy**, Milind Pendharkar, VP, Corporate Development, Kelowana, British Columbia, CAN. **Letter undated** - Milind Pendharkar, VP, Canada Direct Pharmacy, responded to the Board's C&D letter. **Letter undated** - signed by Anton Gjerek, Redwood Drugs, responded to the Board's C&D letter.		
NE			
NH	**7/2/03** - No actions have been initiated to date.		**2/04** - Gov. Craig Benson recently outlined a plan to purchase prescription drugs from Canada for inmates in state correctional facilities and Medicaid recipients taking drugs for mental illness. **NH S 434** - The bill establishes a commission to examine the purchase of prescription drugs in Canada. **5/04** - Concord, NH, **American Drug Club** to assist US consumers in obtaining prescription drugs from Great Britain.

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NJ	**10/27/03** - No further actions have been taken as of this date.		**5/12/03** - New Jersey Legislature **bill No. 570 Section 34 (b)** addressing pharmacists was amended to prohibit the shipping of Canadian and unapproved meds to NJ. **5/22/03** - amendment prohibiting the shipment of Canadian/unapproved meds is dropped.
NM			
NV			
NY	**7/03/03** - Investigations have been initiated. **10/27/03** - NY has closed Canadian drug storefronts either by issuing letters of warning or obtaining orders to shut them down.		
OH	**11/00** - Cease and desist order issued against **Provincial Pharmacy, Inc**, in Windsor, Ontario, CAN. Basis: unlicensed shipping of prescriptions to OH residents. **7/03** - No recent actions initiated to date.		
OK	**3/27/03** – The state authorities filed a petition in OK state court alleging that **Rx Depot** is illegally operating an unlicensed pharmacy. **6/3/03** - State court granted a temporary restraining order against **Rx Depot,** which becomes effective on approximately 8/31/03 so that **Rx Depot** may appeal. Judge's order stated **Rx Depot** violated state statutes.	**3/27/03 - FDA** issued a statement strongly supporting the filing by the OK SBOP and the OK AGO of a petition for injunction seeking to stop the Rx Depot storefront pharmacy from violating state law. **4/10/03** - the **Manitoba Pharmaceutical Association (MPA)** in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of **Northgate Clinic Pharmacy**, 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The MPA received a copy of the court document filed in the District Court of OK (case # CJ-2003-2643) describing the conduct of **Rx Depot** in the state of OK being in violation of state law. The warning letter states that **Northgate Clinic Pharmacy** must immediately cease business agreements with **Rx Depot** in any state and the shipment of medication into the state of OK. **10/27/03** - Federal prosecutors sued storefront operator, **Rx Depot, Inc.** of Tulsa, OK. The case is in US Dist. Court, in Tulsa, OK. Prosecutors claim the company illegally helps import drugs from Canada.	

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OK		**11/6/03** - Federal District Court in OK granted the FDA a preliminary injunction against **Rx Depot, Inc**, and **Rx of Canada** which, the Judge declared, violated the law.	
OR	**7/2/03** - No actions have been initiated to date; however, the Board has ongoing investigations. **10/27/03** - Board sent warnings to eight storefronts recently. **10/30/03 - City of Roseburg** refused to issue a business registration to a storefront and the BOP sent a warning letter to the same storefront: **Canada Drug Supply**.		
PA	**10/15/03** - No action to report by PA Board.		
PR			
RI	**2002**- Cease and desist order sent to two Manitoba pharmacies. Complaint sent to MB pharmacy regulators regarding MB pharmacies shipping to RI. **11/25/03** - RI Board of Pharmacy sent a C&D letter to **Prescription Discounters, Inc. and MediMart Pharmacy**. Board accused the storefront of helping customers order prescription meds from Canada. **MediMart Pharmacy** in Winnipeg, Manitoba fills the order and ships the medication directly to the customer's home.		**2/03** – Legislation introduced to **allow** Canadian pharmacies to ship prescription meds to RI. Legislation, backed by RI Medical Society, would allow BOP to license CAN pharmacies. BOP ED Cordy said Board would oppose the bill. **2/04 - RI H 7320** - This bill, which is being considered by the House Committee on Health, Education and Welfare, would allow pharmacies licensed in Canada to obtain licensure from the state health department.
SC	**2003**- Warning letters sent to several storefronts.		
SD	**2002-2003** - Board sent cease and desist letters and has phoned Canadian pharmacies to inform them of their illegal shipping of meds into SD. Board has also warned **Nuway**, an insurance agent that was providing seminars and assisting seniors in purchasing meds from Canada. **2002-2003** - Complaint sent to MB pharmacy regulator concerning MB pharmacies shipping to SD residents.		

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TN	**10/02** – State sent cease and desist order to **CanadaDiscountRx**. **1/03** - C&D letter sent to **Canadian Rx Consultants Group**, Maitland, FL. **3/03** - C&D letter sent to **Canadian Drugs2U**, Nashville, TN. No response yet; Board is considering next action. **4/03** - C&D letter sent to **Global Pharmacy Rx**, Cookeville, TN. Owner advises that they are no longer in business. **5/03** - Board stated that facilitating the importation of Rxs for Canadian pharmacies is the practice of pharmacy and storefronts should be licensed. **5/03** - C&D letter sent to **Medi Save**, Knoxville, TN. Attorney for the owners of Medi Save advises that they are no longer in business. **5/03** - C&D letter sent to **RealFast** of Winnipeg, Manitoba, CAN. **6/03** - C&D letter sent to **Canada Direct Pharmacy, LTD**, in Calgary, Alberta, CAN. No response.		**1/04** - Legislation introduced, **House Bill 2173**, which requires governor and state insurance committee to request federal approval for importation of prescription drugs from Canada by pharmacy benefits managers; proposal to contain protections to ensure only quality prescription drugs are imported.
TN	**7/9/03** - C&D letter sent to two **Pak Mail** storefront locations representing **CanadaValueRx.com** in Manitoba. Advised by the owner of **Pak Mail** that he had discontinued the practice. No response from **CanadaValueRx**. **7/7/03** - C&D letter sent to **ThriftyMedsNow.com**, Manitou, Manitoba, CAN. Phone calls to the office indicate that they have complied with the order. Consumers (approx. 20) stated that they have been informed by reps of **ThriftyMedsNow** that TN is the only state that has taken an action and the company advised customers to have their meds mailed to another state where it is "legal." **9/11/03** - C&D letter sent to **Canadian Rx Depot**, Winnipeg, Manitoba, CAN. No response. **9/11/03** - mailed a second C&D letter to **CanadaDiscountRx.com**, aka **McKnight's Pharmacy**, Winnipeg, Manitoba, CAN. No response.		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
TN	**9/17/03** - Closed complaints on **Century Advantage**, a storefront representing **Canadian Discount Pharmacy**, and **MediSave**, a storefront representing an unidentified Canadian pharmacy. The board was advised that these locations had complied with a previous C&D letter. **9/30/03** - C&D letter sent to **AccessCanadianPharmacy.com**, aka **Total Care Pharmacy**, West Hillhurst 100, Calgary, Alberta, CAN. No response. **1/30/04** - As of this date, the board has not received a response to a number of C&D letters.		
TX	**7/03** - The Board will send C&D letters to any facilitators who receive or process prescriptions, and any person or business that uses the word "pharmacy," or graphical representations of the same. **7/3/03** - TX SBOP mailed nine (9) C&D letters. A 10th C&D letter will be mailed soon. **8/5/03** - as of this date, Board has mailed twelve (12) C&D letters.		
TX	**As of 10/22/03**, the TX BOP has mailed twenty C&D letters, mailed between 6/30/03 and 10/21/03. The six (6) most recent C&D letters were mailed to the following storefronts: **9/24/03 - Rx Source**, Dallas TX; **9/26/03 - Canada Drug Service of West TX**, Amarillo, TX; **9/30/03 - North America Drug Co**, San Antonio, TX; **10/8/03 - Canadian Rx Depot**, Inc, Denton TX, **Canadian Prescriptions Direct,** Houston, TX; and **10/21/03 - Rx Depot**, Waco, TX. **1/22/04 - Expedite-Rx** was directed by the Texas State Board of Pharmacy last July to "immediately discontinue receiving/processing prescription drug orders."		

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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
UT	**7/02** - C&D Order issued to **Rx North America**. **4/03** - C&D Order issued to **Discount Prescription Service**, a facilitator. **4/03** - Complaint filed with the **College of Pharmacists of British Columbia** against a B.C. pharmacy that appeared to be shipping prescriptions into UT. **4/03** - Complaint filed with the **College of Physicians and Surgeons of British Columbia** against a doctor allegedly prescribing medications for export to UT.		
VA			**1/04 - John O'Bannon (R)** of Virginia proposed legislation **(HR 632)** that provides criminal penalties for those businesses that assist individuals in obtaining prescription drugs from businesses that are not licensed in the US. **2/04 - VA H 190**, in consultation with the Office of the Attorney General and the Executive Director of the Board – D59the bill calls for evaluation and implementation, if feasible and cost effective and consistent with federal law and regulation, a process for purchasing reduced-cost prescription drugs from Canada for some state employees.
VI			

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
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VT	**6/03** - "Position Paper on the Reimportation of Foreign Prescription Drugs" is published in the Vermont Board of Pharmacy Newsletter. **7/03** - The Board currently has two (2) Investigations open regarding Canadian Internet pharmacies. The allegations are: one is a storefront, the only one believed to be in VT; and the second involves a firm that has come to VT, advertised a "Canadian Drug" seminar, and had a pharmacist representing the company at the conference. Both investigations are still open.		**8/1/03** - VT has new rules in the legislative process, slated to go into effect. In the new rules, any pharmacy that ships meds into VT must be licensed by the state. **2/04 - VT SJR 40**, a resolution that passed the House on Jan. 21, 2004, urges Gov. James Douglas to establish a drug importation program for the state. **VT H 502** proposes to require the state of Vermont, municipalities, and school boards to purchase drugs covered by a health benefit plan from Canadian sources.
VT			**VT S 276,** the Senate health and welfare committee will consider legislation that would allow the state department of prevention, assistance, transition and health access to establish a program, Web site and written information to publicize how Vermont residents are able to order drugs through the mail as well as purchasing prescription drugs from Canada.
WA	Several letters have been sent advising Canadian pharmacies not to ship to residents of WA.		**2/04 - WA H 2469** would authorize certain state agencies to purchase prescription drugs, approved by the Food and Drug Administration, from Canadian wholesalers and pharmacies. The health care authority would also develop a Web site to facilitate the purchase of prescription drugs from Canada by Washington residents.

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WI	**7/7/03** - There is one case pending which is against **Philip D. Kuehnl** and **Premium Discount Pharmaceutical Services**. **10/03: Philip Kuehnl** and **Premium Discount Pharmaceutical Services** were enjoined from using or displaying a symbol or insignia having the same or similar meaning as "pharmacy", "drugstore", "apothecary" or any other title without having obtained a pharmacy license.		
WV	**5/13/03** - Cease and desist letter sent to **Discount Prescription Center of WV**, a storefront. **Discount Prescription Center** filed an action in court to bar authorities from closing it, claiming it is not a pharmacy. **11/03** - Judge ruled in favor of **Discount Prescription Center**, enjoining the board from closing the business because, the judge declared, its operations are not in violation of WV law. However, business must change its name. DPC uses **CanAmerica Pharmacy in Manitoba** to dispense medications. Board of Pharmacy is seeking to revise its laws and the definition of pharmacy/practice of pharmacy.	**2/18/04** - the FDA sent a warning letter to Ms. Carole Becker, President, **Discount Prescriptions from Canada, Inc,** 709 Benoni Ave, Fairmont, WV 26554. **Discount Prescriptions from Canada** uses **CanAmerica**, located in Manitoba, Canada, to fill prescriptions and sends the drugs directly to the US consumer. **3/04 - Discount Prescriptions from Canada, Inc**, in Fairmont, WV, stopped its service of helping consumers buy prescription meds from Canada.	
WY	**6/3/03** - Board sent cease and desist letter to **Canada Direct Pharmacy** in Calgary, Alberta, CAN, which sent advertising to St Anthony Manor in Casper, WY. Any pharmacy desiring to do business in WY must be licensed by the Board. **7/03** - Board sent a cease and desist letter to **ThriftMedsNow Pharmacy** in Manitoba, CAN, due to its being an unlicensed pharmacy that is advertising in a Wyoming paper. **8/27/03** - Board sent a C&D letter to **AccessCanadianPharmacy.com**, Calgary, Alberta, CAN, re advertising or dispensing prescription drugs in WY.		

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	FEDERAL ACTIONS		
	FDA - Cyber Warning Letters to Canadian Pharmacies		
	10/31/01 - www.RxNorth.com; www.OnlineCanadianDrugstore.com (MediPlan)		
	10/31/01 – www.Canadameds.com (Point Douglas Pharmacy)		
	11/15/01 – www.Canadarx.net (Target Zone)		
	9/9/03 - The **FDA** has asked the DOJ to file a complaint for injunction against **Rx Depot, Inc.**, and **Rx of Canada, LLC** (Rx Canada), to stop them from importing drugs that pose a serious threat to the public health.		
	11/6/03 - FDA sent a letter warning **CanaRx**, a company supplying prescription drugs to Springfield, MA, that its operations are illegal under federal law. **11/6/03 - FDA** sent a detailed letter informing the state of Illinois that its report, which reviews the feasibility of and recommends importing prescription medications from Canada, is potentially in violation of federal and state law, is flawed, and that unregulated importation endangers people's lives. **1/9/04** - The **FDA** is not ruling out legal action if cities of states defy its ban on importing cheaper drugs from Canada, per Commissioner McClellan.		
	1/22/04 - The FDA issued a warning letter to **Expedite-Rx**, a PBM; **SPC Global Technologies**, Ltd, an insurance claims processor; and **Employer Health Options, Inc**, an insurance company, all of Temple, TX, notifying them that it considers their drug import program to be illegal and a risk to the public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada. Expedite-Rx, SPC Global Technologies, and Employer Health Options have 15 working days to inform FDA about the specific steps they will take to bring their operations in full compliance with US law. In case of non-compliance, FDA may take legal actions, including seizure and/or injunction, without further notice.		
	ACTIONS TAKEN BY CANADIAN REGULATORY AGENCIES **May 2002** - The **Ontario College of Pharmacists**, the regulatory body for enforcing pharmacy practice standards, charged **The Canadian Drugstore, Inc,** with 15 different violations, including operating an unlicensed Internet pharmacy without registered pharmacists from November 2001 to February 2002. **March 2003** – Cross-Border Statement was issued by **Nova Scotia College of Pharmacists** stating, among other things, that Nova Scotia pharmacists and pharmacies should not participate in any scheme or service to accommodate importation of Canadian medications by US citizens. Pharmacists/pharmacies that accommodate such services may be found to be practicing unethically and may be found guilty of professional misconduct. **April 2003** – Canadian Broadcasting Corporation (CBC), Fredericton – The **New Brunswick College of Physicians** has suspended the license of **Dr Andre Loiselle**, a physician accused of helping to sell prescription drugs over the Internet. Dr Loiselle wrote prescriptions for a Web site that markets drugs to senior citizens in the US, even though he had never met the patients.		

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	April 2003 - The **Manitoba Pharmaceutical Association** (MPA) in Winnipeg, Manitoba, CAN sent a "warning letter" to **Derek Chan**, Pharmacy Mgr of **Northgate Clinic Pharmacy**. The warning letter states that **Northgate Clinic Pharmacy** must immediately cease business agreement with **Rx Depot** in any state and the shipment of medication into the state of OK. **July 2003** - The **Ontario College of Pharmacists** (OCP) resolved its prosecution against **The Canadian Drugstore Inc**; **Rep-Pharm, Inc**; **Stephen Bederman, RPh**; and **Dr Stanley Gore** and his company **Canadian Custom Prescriptives, Inc**. Summary of charges involved: unlawful dispensing or selling of a drug to a patient; operating an unlicensed pharmacy; and dispensing a prescription without written authorization of a Canadian doctor. The specific judgment follows in paragraphs 1-3, below:		
	1. **The Canadian Drugstore, Inc**, pled guilty on 6/23/03 to one offense contrary to the Regulated Health Profession Act, 1991 (RHPA), and four charges contrary to the Drug & Pharmacies Regulation Act (DPRA). The **Ontario Court of Justice** fined the company (Canadian Drugstore, Inc) $20,000. This fine amount was part of an overall disposition that included a $125,000 payment by the Canadian Drugstore, Inc, to the Leslie Dan Faculty of Pharmacy, University of Toronto, to establish the Ontario College of Pharmacists' Professorship in Pharmacy Practice. 2. **Rep-Pharm** was fined $5,000. 3. Charges against the RPh **Bederman**, **Dr Gore**, and affiliated companies were dropped; however, the pharmacist faces a disciplinary hearing on December 2003, and the doctor was referred to the **College of Physicians and Surgeons of Ontario** for a hearing and determination.		
	10/31/03 - Four Manitoba doctors have been reprimanded by their professional organization for countersigning prescriptions for U.S. patients seeking Canadian drugs through Internet pharmacies. Registrar of the **College of Physicians and Surgeons of Manitoba** stated the disciplined doctors were **Raj Vijay**, **Michael O'Sullivan**, **Alexander Wilson**, and **Henry Dirks**. The four doctors were censured 9/15/03 after the college investigated. The doctors have allegedly stopped cosigning prescriptions; however, should they do so again, they could face more severe penalties. **11/03 - NAPRA** issued a statement requesting that the Canadian federal government ban the exportation of prescription medications to the United States.		
	5/4/04 - Manitoba Pharmaceutical Association recently upheld a discipline committee's earlier finding that pharmacist **Andrew Strempler** of **Mediplan Health** violated the Pharmaceutical Act by filling more than 10,000 prescriptions for American patients that were written by doctors who were not licensed to practice in Canada. Strempler has asked the court to stay the Association's decision pending the outcome of the current appeal and then to overturn the ruling under provisions of the Act.		

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Giuliani Partners LLC
Examination and Assessment of
Prescription Drug Importation From Foreign Sources
To the United States

Interim Findings
May 11, 2004

INTRODUCTION

The availability of safe, effective and reasonably priced medications for all Americans is at the center of an important, ongoing debate regarding our health care system. As the costs of medicines have increased, so has the focus of pricing on this debate. Individuals and even local and State governments have sought alternative means to obtain necessary medicines at lower costs, and these initiatives have further narrowed the debate to the value of importing Canadian or foreign medicines into the United States.

However, the safety and efficacy of these same imported medicines has received less attention and focus and is often overshadowed or even ignored by the pricing issue. From the outset, there is little dispute that the high price of many prescription medicines becomes an impediment to access. And while the price of today's medicines exist in part to provide for the development of tomorrow's cure, patient access should be expanded by exploring methods for lowering costs for those in need.

Giuliani Partners LLC has been retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to evaluate the risks, if any, associated with the importation of Canadian and foreign medicines.

In recognition of the public health implications associated with importation, and at the request of Congress, the United States Department of Health & Human Services has convened a Task Force on Drug Importation to examine these very concerns. Acknowledging the importance of this issue to the public, the Task Force is working with great alacrity to provide its recommendations to HHS. Giuliani Partners LLC will be providing the Task Force with a more detailed report encompassing our preliminary findings and conclusions as part of our effort to inform this critical debate and to assist the Task Force in its work. For now, we have made a series of interim findings that are worth discussing today to widen the lens through which the issue of the importation of drugs is viewed, and consequently address the equally important issues of safety and risk in the Task Force's assessment.

It is important to note from the outset that there appears to be a fundamental misunderstanding about the source of the less expensive drugs at the center of this discussion. Initially, this debate was framed around "re-importation" – in other words, the importation (from Canada) of medicines manufactured under U.S. Food and Drug Administration (FDA) oversight and now available at a lower cost via Canada. Under such a system, a patient could reasonably assume that the medicine

was safely and properly manufactured under FDA oversight without corruption in the supply chain. However, that is not necessarily what is occurring. Instead, U.S. patients are receiving medicines from foreign countries (albeit ordered through Canada or sources purporting to be Canadian based) that were manufactured or re-packaged without any oversight by the FDA or Health Canada (the Canadian FDA counterpart).

Indeed, several U.S. States that provide links to websites for their citizens to order "Canadian" drugs have graphic disclaimers disavowing any warranty about the product and relinquishing the state government from any legal liability with regard to the product or care from the on-line pharmacy. In some instances, the Canadian pharmacy website requires the patient to sign a waiver that denies the patient any legal recourse in the U.S. for harm caused by these imported drugs. The current U.S. regulatory process, while not perfect, protects patients seeking medicines from U.S. pharmacies. This raises an important question that must be reviewed when assessing the relative risks associated with obtaining imported medicines against the potential rewards of lower prices.

Product Quality: What Is In Our Medicine?

When a patient seeks to fill a particular prescription for a particular medicine, there is an assumption that the medicine is in the exact form, quality, potency and dosage as directed by the patient's physician. Anything less constitutes a risk to that patient's health and well-being.

Based upon our review to date, we have found that some patients who believe they are purchasing re-imported Canadian medicines are in fact receiving non-FDA approved drugs from foreign countries that are not at all what they claim to be. There is significant evidence that patients have received drugs through the internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), contain the wrong dose, are contaminated or clearly counterfeited, are not properly stored or shipped (i.e. medicines that require constant refrigeration or others that must be protected from freezing) among other problems. We have found that medicines ordered over the internet that purport to be manufactured under FDA oversight or delivered through Canadian pharmacies are in fact manufactured in countries such as Pakistan, China, Iran, Singapore and many others. The fundamental question of product quality and integrity must be at the center of this important discussion.

Set forth below is an outline of the review we have undertaken. Significant questions are raised regarding the level of safety for patients and indeed for our nation from the relaxation of importation controls. It is vital that the Task Force and others carefully and thoughtfully consider all of these legitimate concerns so that our health care system can be as safe, effective and accessible as possible.

SYSTEMIC ISSUES

The American system for manufacturing, distributing and selling prescription medicines is significantly regulated and often referred to as the "gold standard."

Notwithstanding this fact, however, there are identifiable weaknesses in this process that can compromise the quality and integrity of our medicine supply.

The Distribution Chain

On its face it appears that the distribution chain for prescription medicines in the United States is fairly straightforward – manufacturers sell their products to wholesalers, who in turn sell the products to retail pharmacies or stores, who in turn dispense medicines to patients with prescriptions. It is not until the system is studied in greater detail that one begins to appreciate both the complexities and the vulnerability of the distribution chain and the potential for exploitation or abuse.

Some contributing factors are as follows:

- Wholesalers or distributors are primarily regulated by the states with no uniform standards across state borders. States have a comparatively small number of investigators to monitor the licensed wholesalers; thus, given the sheer number of wholesalers, oversight is minimal.

- There are thousands of "secondary" pharmaceutical wholesalers in addition to McKesson, AmerisourceBergen and Cardinal Health (the "big three") involved in the distribution of prescription medicines. As reported in The Washington Post, there are more than 6,500 small wholesalers nationwide.

- There is no uniform mechanism, i.e., a chain of custody or "pedigree," to track the medicine from point of manufacture to point of sale; the FDA has not implemented the pedigree requirement that was mandated by law in 1988.

- Repackaging is a vulnerable point in the process and can provide an opportunity for counterfeit or non-FDA approved products to compromise the system.

Report of the Florida Grand Jury

Two years ago the State of Florida convened a statewide Grand Jury to examine the safety of prescription drugs in Florida and to analyze the sale and resale of prescription drugs in the wholesale market. The report, released in February 2003, found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution industry. Many of those interviewed by Giuliani Partners indicated that the problems identified in the Florida Grand Jury Report are pervasive throughout the United States. A summary of the Grand Jury's findings follows.

- Oversight of the system is lax.
    - Minimal background checks are required for licensing wholesalers and warehouse operators were found to be uneducated amateurs, some with criminal records.
    - Corrupt wholesalers are neither investigated nor prosecuted.
    - Despite existing requirements, drugs are being distributed with either incomplete or, in many cases, non-existent pedigree papers to document the products' supply chain history.

- Inspection of wholesaler operations by the appropriate authorities and oversight by responsible agencies is spotty at best.

- Funding for oversight agencies is inadequate.
  - The Florida Bureau of Statewide Pharmacy Services employs only nine field inspectors to inspect 422 wholesalers statewide.

- Product quality is compromised.
  - Widespread problems with the quality and integrity of the secondary wholesale drug supply were found to include:
    - expired drugs re-labeled with falsely extended dates
    - previously dispensed medicines
    - illegally imported drugs
    - sub-potent drugs
    - drugs that contained an entirely different substance from the one listed on the container's label

- Health risks are significant.
  - The mainstream market is compromised by corrupt, secondary wholesalers. Diverted drugs are often combined with counterfeit medicines or re-labeled or repackaged. Then, these compromised drugs enter the mainstream market through corrupt secondary wholesalers and are dispensed by legitimate pharmacies, hospitals or clinics. By way of example, a father in Michigan who thought he was injecting his son with a growth hormone later found that the vials actually contained insulin. These drugs were traced to a legitimate pharmacy in Orlando, Florida.

- Incentives for counterfeiting and diversion are considerable.
  - The huge profits derived from these activities rival those of illicit narcotics traffickers, while the penalties are minor by comparison.

Challenges to Oversight and Enforcement

There are challenges associated with the oversight and enforcement of our current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved, safe and effective.

- The current volume of parcels of drugs coming into this country through the mail (it is estimated to be more than 10 million packages annually) and the increasing volume of internet purchases make meaningful inspection by the FDA almost impossible.

- The FDA has less than 100 investigators to deal with drug importation issues nationwide, and its investigative authority is limited relative to its ever-increasing law enforcement responsibilities. For example, the FDA has no administrative subpoena authority in order to facilitate the conduct of its investigations; thus it must either partner with another investigative agency or request subpoenas from the local United States Attorney's office.

- Investigating and prosecuting counterfeit drug cases or illegal internet sales cases are not, with few exceptions, a priority for the federal or state law enforcement agencies.

- The penalties are comparatively low for engaging in this kind of activity – the current penalties for FDA violations are approximately 3 years.

- The technologies being advanced as mechanisms to ensure an imported drug shipment is safe and effective are not foolproof, and, in some instances, not yet available.
    - Electronic Track and Trace – most agree that these technologies, e.g., using bar coding or radio frequency identification (RFID) chips that could track drug products in real time throughout the system and then provide an electronic pedigree, are still very costly when available.
    - Counterfeit resistant technologies that include covert and overt packaging and labeling techniques, such as holograms, watermarks, color shifting inks or fluorescent inks, as well as chemical agents, are widely used by the industry already. However, they can be easily duplicated and, therefore, must be changed on a periodic basis.
    - "Unit of Use" packaging, which is a container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for appropriate labeling, does eliminate the need for some repackaging; however, there are packaging and cost issues for the manufacturers, and some drugs do not lend themselves to such packaging.
    - Authentication testing, while not a technology *per se*, is also an option when determining the integrity of a pharmaceutical product. It is a complicated, time consuming and costly process, however, and can be performed only by the original manufacturer. There are no available tests that can be conducted "in the field" to ascertain whether a product is real or fake.

These factors, among others, make it a high profit, low risk business for the counterfeiters or those involved in circumventing the laws in supplying medicines outside the traditional distribution chain, and, therefore, it may be appealing to organized crime and terrorist organizations.

PRODUCT QUALITY

Weaknesses in the existing system already threaten the quality and integrity of the nation's drug supply. Despite best efforts, the evidence we have seen thus far supports the notion that the drug supply is indeed vulnerable. Some examples are as follows:

Random Examinations Conducted by the FDA and U.S. Customs and Border Protection

The FDA and U.S Customs and Border Protection conducted a number of random inspections or "blitzes" at several mail ports in the fall and early winter of 2003.

- In the first inspection, 1,153 drug products were examined and 1,019 or 88% were not approved by the FDA; the drugs came from countries such as India, Thailand, and the Philippines.

- In the second exam, 1,982 parcels were examined and 1,728 or 87% were not approved; 16% of those shipments were from Mexico.

- Many of the drugs examined during these visits were non-FDA approved for many reasons, including:
  - improper labeling, e.g., there were no instructions for proper use;
  - the presence of controlled substances;
  - potentially recalled drugs, e.g., drugs that had been withdrawn from the market for safety reasons;
  - animal drugs not approved for human use;
  - drugs requiring risk management and/or restricted distribution (e.g., initial screening or periodic monitoring); drugs with clinically significant drug interactions; or drugs requiring careful dosing; and
  - required special storage conditions for certain drugs were violated.

Portal Visits

In order to gain an appreciation for the scope of the problem, United States mail facilities were visited to observe the volume and nature of the packages allegedly containing prescription drugs entering the United States. A number of the observations follow.

John F. Kennedy Airport Mail Facility

At the invitation of United States Senator Norm Coleman, former New York City Mayor Rudolph W. Giuliani and former New York City Police Commissioner, Bernard B. Kerik, accompanied the Senator on a visit in March, 2004 to the US Mail facility located at JFK Airport. Customs officials advised that approximately 40,000 packages of suspected drug shipments are received each day from the postal service for review and inspection. Based upon information, the FDA focuses on "countries of interest" and visually inspects 500 to 700 parcels per day. Thus, the majority of packages are sent on to the addressee uninspected. The following was learned:

- Drugs purported to be Xanax, Valium (Diazepam), Lorazapam, Vicodin (all controlled substances) and Lupron were observed; there were numerous packages from the Netherlands, Brazil, Pakistan, as well as other countries.

- Many of the drugs contained in the parcels were non-FDA approved because they were inappropriately packaged, expired, mislabeled or otherwise noncompliant.

- The sheer volume of shipments overwhelms Customs and FDA; FDA has only 6 staff members assigned to JFK.

- Although much of what is inspected is non-FDA approved, few parcels are actually detained. The processing requirements to detain a shipment are

cumbersome and time consuming. The rules require the FDA to send a notice to the addressee of the package. If the person does not respond or the response is insufficient, the package must then be returned to the sender (manufacturer). This process varies significantly from the way controlled substances or narcotics are handled. Such drugs can be destroyed without further processing.

Miami International Mail Branch Facility Visit in March 2003

Giuliani Partners was provided with a Congressional staff report regarding a similar review of the Miami facility in March 2003. The findings of the bipartisan Congressional report were consistent with the findings of this review:

- Congressional staff witnessed "thousands of shipments of foreign drugs" being processed; the packages were from countries such as Honduras, Costa Rica as well as Great Britain; and the packages purportedly contained "valium" (diazepam), Reteina (Ritalin), Zolipedem, and Ciprofloxacin.

- The volume of drugs coming through the mail facilities is too great to allow for any meaningful inspection.

- Parcels are only visually inspected; there is no testing as to the quality or integrity of the product.

- FDA and Customs detain very limited numbers of questionable drugs coming into the facility because of the cumbersome nature of the detention process.

<u>The Increase in Counterfeit Drugs</u>

- Most of those interviewed by Giuliani Partners agreed that:

    - The number of incidents involving counterfeit medicines is increasing;
    - The increased use of internet sale and purchase is exacerbating the problem;
    - The counterfeiting techniques are becoming more sophisticated and harder to detect;
    - There are vulnerabilities in the current distribution system that contribute to the problem; and
    - Opening the borders for wholesale importation will worsen the problem.

- The former Commissioner of the FDA, Dr. Mark McClellen, testified before the U.S. Senate Committee on Commerce, Science and Transportation on March 11, 2004 that the FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990's. "Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well funded and elaborately organized networks."

- On its website, the World Health Organization (WHO) states that while the true extent of the problem of counterfeit drugs is difficult to know or measure,

they have estimated that at least 8% – 10% of the world's total drug supply is counterfeit.

- An August 30, 2002 Washington Post story cites the Shenzhen Evening News in reporting that an estimated 192,000 people died in China in 2001 because of counterfeit drugs. Another news story reported that as much as 50% of China's drug supply is counterfeit (Investor's Business Daily dated October 20, 2003).

Reported Incidents of Adverse Effects

Without question, the most frequently asked question by proponents of importation is "who is really being harmed by the purchase of medicines from outside of the United States?" There appears to be no easy answer to the question. Because receipt of imported medicines is unregulated, there are no systems in place to effectively monitor whether injuries result from the taking of compromised medicines. When complications arise from taking imported medicines and a patient does consult with his or her doctor or reports to an emergency room, no one is asking the question 'where do you purchase your prescription medicines?" Patients are also reluctant to report adverse reactions that may be attributable to medicines illegally purchased from outside the country.

Given these circumstances, coupled with the systemic challenges discussed earlier, it is difficult to ascertain the actual source of an imported drug. The following are some examples of actual incidents where people taking medicines with undocumented origins were adversely affected as a direct result of taking the prescription drugs. These cases represent the dangers of obtaining drugs from sources outside of the United States' closed system.

- In La Mesa, California, Ryan T. Haight, 18, died in his bedroom of an overdose after taking narcotics obtained on the internet. After his death, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. An investigation by federal drug agents showed that the teenager had been ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay. (Washington Post, October 19, 2003)

- In Sacramento, California, James Lewis, 47, a former triathlete, shopped the world for painkillers that flowed unimpeded from pharmacies in South Africa, Thailand and Spain. His wife discovered him dead of an overdose on the living room couch. (Washington Post, October 19, 2003)

- A 15-year-old paraplegic boy went into convulsions and died after taking a non-FDA approved drug called Lincocin which had been smuggled in from Mexico. (Los Angeles Times, March 10, 2001)

- Juris Abolins, 43, used painkillers off and on for years to treat pain from kidney stones. His roommate found him slumped on his bedroom floor dead. An autopsy revealed the presence of controlled substances in his blood stream.

Relatives found a Federal Express slip for drugs purchased from a website in Tijuana, Mexico. (Washington Post, October 19, 2003)

THE INTERNET

Over the past several years, hundreds of websites have appeared on the internet selling prescription medicines. While some sites provide legitimate prescription services, many sites are illegitimate and pose significant risks to all patients who use them.

Private Investigation Regarding Internet Purchases

A security and investigative firm based out of New York City, Beau Dietl & Associates, conducted an investigation regarding the importation of foreign medicines and reported its findings in December 2003. The results were disturbing:

- More than 1400 websites were identified as selling prescription drugs.
- 352 of those sites did not require a prescription when ordering.
- 142 of 170 orders were placed without a prescription and at the time of the report, 79 orders were filled without a prescription.
- Many of the medicines received were not only shipped in improper packaging but came from foreign countries such as Pakistan.
- An order for Ciprofloxacin was placed, received and tested. It was determined to be only 65% potent.
- The investigation found that website operators were often difficult to identify and trace; and some of those identified were found to have questionable backgrounds:
    - One website owner/operator was a convicted felon;
    - Other website owners could not be traced because the registration information was false;
    - Many sites failed to comply with legal requirements – doctors wrote prescriptions without ever meeting the patient; and one internet doctor was a convicted sex offender.
- Websites were easily established with no minimum qualifications, standards, or oversight.
- Once the websites were established, emails were received from various suppliers offering to provide medications from "several countries," or "bulk meds from Pakistan" for resale in the U.S. market.

The results of this investigation offer a troubling snapshot of the nature of the internet pharmaceutical business.

The CASA White Paper

The National Center on Addiction and Substance Abuse at Columbia University, under the direction of Joseph Califano, former Secretary of the Department of Health, Education and Welfare, the predecessor of the U.S. Department of Health and Human Services, released a study in February 2004 regarding the sale of controlled, dangerous and addictive prescription drugs in America. It looked particularly at internet sales and teamed with the same New York City investigative firm to conduct the review. CASA characterized its findings as "alarming."

During a one-week period of observation, the firm identified a total of 495 web sites offering Schedules II through V controlled substance prescription drugs. Examples of the controlled substances available online included painkillers, stimulants, and nervous system depressants.

- Of the 157 sites selling controlled substance prescription drugs on the internet
  - 90% (141) did not require a prescription
  - 4% (7) required that a faxed prescription
  - 2% (3) required that a mailed prescription
  - 4% (6) made no mention of prescriptions

- Of the sites, 47% disclosed that the drugs would be coming from outside the United States; 28% stated the drugs would be shipped from a US pharmacy; and 25% gave no indication where the drugs would be coming from.

- The analysis determined that there were no mechanisms in place to block children from purchasing these drugs.

Canada – The Implications of Importation

It is generally agreed that prescription medicines purchased by Canadians in a Canadian drug store are safe and effective. Like the United States, Canada has a system of regulatory controls over its medicine supply. However, the same cannot be said for the drugs that are being imported to Canada and then exported. In fact, the Canadian government is not inspecting those medicines that are being imported to Canada and then exported to the United States. The Canadian government has clearly stated that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country. Furthermore, the Canadian Food and Drug Act does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada.

With respect to the question of drug supply capacity, it is undisputed that Canada does not have supply sufficient to provide for its residents and Americans as well. (In 2002, 3.1 billion prescriptions were filled in the U.S. compared to 335 million prescriptions filled in Canada.)

According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others. Further, some Canadian pharmacies, such as Canadameds.com, have publicly indicated that because of the increasing demand from the United States, they are turning to Great Britain for prescription drugs.

THE POTENTIAL FOR EXPLOITATION BY NARCOTICS TRAFFICKERS, ORGANIZED CRIMINALS AND TERRORISTS

The terrorist attacks of September 11, 2001 demonstrated how vulnerable this country is to those who have total disregard for human life or who mean us harm. Since that time, the United States has invested billions of dollars to protect our borders. Despite all that has been done, we have not focused on the vulnerability of the nation's medicine supply as a potential target. The present controlled system of importation and inspection is open to exploitation and abuse. Any further removal of controls, much less the total opening of the borders to foreign drugs, would create a situation that terrorists, drug dealers and organized criminals might well use to their advantage. It seems counter-intuitive to contemplate opening our borders with regard to our medicine supply when in all other aspects of border security and protection, we as a country are looking for ways to tighten security.

A July 22, 1998 story in Insurance Day, while reporting on pill piracy and the World Health Organization's efforts to confront pharmaceutical fraud, stated that "Interpol believes that this aspect of the drug trade is closely connected with the narcotics cartels and that the profits generated by it are in part used to finance international terrorism." The article further stated that Interpol had been following the global counterfeit drug racket for some time and based its belief on evidence uncovered by police in North America and Western Europe.

Further, in her book, Funding Evil, How Terrorism is Financed – and How to Stop It, Rachel Ehrenfeld makes numerous references to the fact that terrorists use counterfeiting activities as a means to fund their terrorist acts. While counterfeit prescription drugs are not specifically referenced, the use of illegal drugs to fund such activities is well documented.

GlobalOptions Inc. identified the potential terrorist threats to America's medical supply in its work, An Analysis of Terrorist Threats to America's Medicine Supply. In sum, it identified three potential threats. First, the "mere infiltration of terrorists in the counterfeit drug market poses a threat to the public." Terrorists could easily produce and sell harmful prescription drugs. Second, terrorist groups could use the profits raised through the sale of counterfeit or diverted drugs to fund their activities. And third, terrorists could use poisoned drugs as a method of attack or, worse, as a weapon of mass destruction.

This study cited numerous examples of links between counterfeiting activities of various types and terrorist groups, where such groups were using the proceeds from these sales to fund their terrorist activities. In particular, the authors pointed to the following:

- The activities of the Irish Republican Army in the early 1990's in Florida that included the manufacture of a counterfeit drug product used to treat livestock. Proceeds from this operation were used to purchase guns;

- An international drug ring raised millions of dollars for Hezballah. The report states that the terrorist group's operatives legitimately purchased large quantities of pseudoephedrine in Canada, smuggled it into the United States, and produced "speed."

THE CONCLUSION

After conducting a preliminary, independent review of the issues associated with the wholesale importation of prescription medicines, it is evident that the existing pharmaceutical system is open to significant exploitation of counterfeit, diluted or adulterated drugs coming into the United States. The limitations of our system should be addressed before it is opened to wholesale importation.

The Health and Human Services Task Force on Drug Importation is currently considering all of these issues. The Task Force should be allowed to complete its mission as Congress directed before any major statutory changes are contemplated. Given the seriousness of this issue and its implications for the health and safety of Americans, a thorough and well-informed analysis is necessary.

Our interim findings can be summarized as follows:

- Although the current pharmaceutical manufacturing and distribution system is comprehensive and regulated, counterfeit or otherwise adulterated products still penetrate the market.

- There are serious questions as to the quality and safety of the medicine products coming into the United States from foreign sources.

- There are no minimum standards and little or no regulation regarding the operations of internet pharmacies.

- There are identifiable weaknesses in the current pharmaceutical distribution chain (e.g., the "secondary" wholesale distribution market and the lack of a drug pedigree)

- The agencies responsible for enforcing the existing laws and regulations are already overwhelmed with the current volume of non-FDA approved prescription medicines coming into the United States.

- The potential exists for the use of the nation's medicine supply as a vehicle for terrorist activity.

- There are serious implications for Canadians with the current demand on their drug supply.

As noted previously, this review and these findings are preliminary. However, the issues discussed herein strongly suggest that no action be forced on the FDA or other government oversight agencies until the HHS Task Force has completed its analysis. In the meantime, the public should be made aware of the risks associated with importing medicines from outside the United States. As the importation debate continues, it is vital that all aspects of this important public health issue be carefully assessed. We should not minimize the potential risks surrounding importation.

Merrill R. Jacobs
Deputy Vice President
State Government Affairs

PhRMA

April 15, 2004

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814

CALIFORNIA STATE BOARD OF PHARMACY
2004 APR 22 PM 12: 18

RE: Importation of Illegal Drugs

Dear Members:

The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully urges you to oppose facilitating the purchase by California residents of prescription drugs from Canadian pharmacies.

As confirmed by the U.S. Food and Drug Administration (FDA), importing drugs from abroad is unsafe and violates federal law that exists to protect patients from illegal, contaminated and counterfeit products. Virtually all drugs imported into the United States, other than those imported by the original manufacturer, pose serious safety concerns. To illustrate, a recent U.S. Customs and FDA investigation found that 88% (1,019 of 1,153) of imported drugs contained unapproved drugs, such as mislabeled, misbranded, expired, and mishandled drugs that might cause patient health problems.

The drug importation programs by proposed legislation or regulation would likely cause the state to suffer potential liability if recipients of foreign drugs were injured by these imports.

As a general matter, it is unlawful under the Federal Food, Drug, and Cosmetic Act for the state or anyone to import a drug into the United States that is not approved first by the FDA. Violating federal law invites FDA enforcement actions. Not only is it illegal for a state to import an illegal drug into the United States, it is also illegal for a state to even *cause* the importation. Even if a state structures a program so that patients themselves are importing drugs for their personal use, it is still illegal. To this end, I attach a letter dated August 25, 2003 from the FDA to the Deputy Attorney General in California concerning FDA's position on the legality of acquiring drugs from a foreign source for importation into a state.

I am also attaching a legal opinion raising issues of state liability for importation of such drugs.

Thank you for your consideration.

Respectfully,

Merrill R. Jacobs
Deputy Vice President

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October 3, 2003

LIABILITY OF STATES IMPORTING PRESCRIPTION DRUGS FROM CANADA

This memorandum evaluates the potential liability that could be incurred under recently announced proposals by certain state governments to import prescription drugs from Canada. This memorandum also addresses the legality under the Federal Food, Drug, and Cosmetic Act (FDCA) and other laws of such proposals. For the reasons discussed below, states could potentially face substantial liability under various tort theories if recipients of Canadian drugs were injured by these imports. Further, these proposals implicate core provisions of the FDCA and are illegal, as FDA has itself made clear. Serious questions also exist as to whether drugs imported from abroad may be reimbursed under Medicaid or Medicare. In addition to these legal issues, strong public policy and public health grounds exist to support enforcement action against such programs.

Drugs Imported from Canada May Pose Serious Dangers to Patients

FDA recently announced that a series of spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous unapproved or counterfeit drugs that pose potentially serious safety problems. FDA's press release describing the results of these examinations is available at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html. Of 1,153 imported drug products examined, 88% constituted unapproved drugs, many of which could pose clear safety problems. Over fifteen percent of the drugs examined entered the U.S. from Canada.

While it is commonly perceived that drugs imported from Canada can be safely substituted for their American counterparts, FDA's examinations revealed serious safety concerns about a number of Canadian imports. For example, the agency found that taro-warfarin, an apparently unapproved version of Warfarin®, is being imported from Canada. Warfarin is used to prevent blood clotting and its potency may vary depending on how it is manufactured. Because it can cause serious, life-threatening bleeding if not administered appropriately, it requires careful monitoring by a health care provider of a patient's blood count during treatment. Use of imported taro-warfarin that differs in potency from Warfarin could substantially interfere with a patient's treatment. FDA expressed similar concerns with unapproved Canadian versions of Synthroid® and Glucophage®, which also require individual titration and very careful dosing to avoid serious life-threatening side effects. FDA also noted that unapproved versions of Zocor® from Canada are being imported and have the potential to cause clinically significant interactions with other drugs which consumers may be taking.

FDA's examinations of these products reveal that Canadian drug imports may pose real and serious health risks to patients taking them.

State Tort Liability for Injuries Suffered by Patients Using Canadian Drugs

The potential tort liability that a state could face for providing or facilitating the provision of Canadian drugs to patients who are subsequently harmed by the drugs is illustrated by examining the law in two particular states -- Massachusetts and Illinois. States, of course, have not previously engaged in these types of activities, and thus there is not case law that addresses the precise circumstances that would be presented by a state drug import plan. Nonetheless, as discussed in the following sections, clear potential causes of action could lie where patients are harmed from a foreign-sourced drug. Such harm could occur, for example,

where the potency of the imported drug is not the same as that of the FDA-approved drug for which it is intended to substitute, resulting in an over- or under-dose, or where the import causes side effects or dangerous interactions that would not be expected with the FDA-approved version.

States that provide Canadian drugs directly to patients or that facilitate the provision of these drugs, through a state-sponsored pharmacy benefit plan or by other means, thus face real risks of liability, including under the tort theories of negligence, strict liability/breach of implied warranty of merchantability, failure to warn, and fraud or misrepresentation. Using our illustrative examples of Illinois and Massachusetts, the states would not be immune to such liability. The Illinois Court of Claims Act (705 ILCS 505/9) and Chapter 258 of Massachusetts General Laws expressly allow for causes of action against the state for damages in cases sounding in tort (Illinois) and for state liability for personal injury or loss of property (Massachusetts). Those statutes do, however, impose conditions and procedures for tort actions brought against the states.

A. Negligence

Negligence is the failure of a responsible person to exercise the degree of care required to discharge the duty resting on him. *Nelson v. Massachusetts Port Authority*, 771 N.E.2d 209, 211 (Mass. App. 2002). The elements of a negligence action are a legal duty of reasonable care owed by defendant to plaintiff, a breach of that duty, and injury proximately caused by that breach. *See Id.*; *Swett v. Village of Algonquin*, 523 N.E.2d 594, 597 (Ill. App. 1988). A state that provides or aids the distribution of Canadian drugs to patients ultimately harmed by them could face serious liability for negligence.

The state would likely be deemed to owe a duty to the patient to ensure that drugs provided or procured are safe for their intended use. Whether a legal duty exists involves consideration of legal and social policies, including foreseeability and likelihood of injury, magnitude of burden of guarding against injury, and consequence of placing that burden on the defendant. *Swett*, 523 N.E.2d at 597; *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 819 (Mass. 2002). It is likely that the states' police power to regulate the public health and welfare would be considered to give rise to a duty to refrain from affirmatively providing potentially unsafe drugs to state citizens.

The duty owed by a state to its employees is even more plain as a matter of social policy, and in Illinois is statutory. The Illinois Health and Safety Act, which expressly applies to the State of Illinois and all political subdivisions as employers (820 ILCS 225/2), provides that "[i]t shall be the duty of every employer under this Act to provide reasonable protection to the lives, health and safety and to furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees." 820 ILCS 225/3(a) (2003). While this provision may have been intended to apply to workplace safety, its wording is broad enough to potentially cover the provision of drugs, directly or through a pharmacy benefit plan, to employees.

The injury to patients could be considered both foreseeable and likely, given FDA's longstanding insistence that such drugs are unsafe, including the agency's most recent report of its examination of imported drugs. A state's provision of drugs it knows to be potentially harmful would likely constitute a breach of its duties to its employees and other citizens, particularly if it provides the drugs to patients directly. *See Shuras v. Integrated Project*

Services, Inc., 190 F. Supp. 2d 194, 200 (D. Mass. 2002) (seller is liable for negligence if it knew or had reason to know of the dangerous condition that caused plaintiff's injury).

Harm resulting from that breach could be shown by evidence demonstrating that the patient's injury was caused by the Canadian drug. The harm could be attributable to the state as either the direct provider of the drug or as the facilitator of the provision of the drug to captive state employees. Attribution of harm to the state may be particularly appropriate because the Canadian drug would not have been legally accessible to the plaintiff through other channels.

Based upon the foregoing considerations, a state that provides Canadian drugs to patients who are then harmed by them could likely be found liable for negligence, because its actions could be deemed a failure to exercise the degree of care required of an entity in the state's position with respect to the patient. It is even possible that the state could be found liable for gross negligence given FDA's repeated pronouncements about the dangers of Canadian drugs.

B. Strict Liability/Breach of Implied Warranty of Merchantability

The contract theory of breach of implied warranty of merchantability is nearly identical to the tort theory of strict liability. *Garcia v. Edgewater Hospital*, 613 N.E.2d 1243, 1249 (Ill. App. 1993). While Illinois continues to recognize both causes of action, Massachusetts has substituted breach of implied warranty under its Uniform Commercial Code (UCC) for the tort principle of strict liability. Strict liability and breach of implied warranty of merchantability may be premised upon an inherent defect in the product itself or upon the defendant's failure to warn. This section addresses liability for product defect; failure to warn is discussed below.

A plaintiff may recover in a strict liability action in Illinois if he or she proves that an injury resulted from an unreasonably dangerous condition of the product, which condition

existed at the time the product left the control of the manufacturer. *Johnson v. Danville Cash & Carry Lumber Co.*, 558 N.E.2d 626, 629-30 (Ill. App. 1990). The rule of strict liability "encompasses the commerce chain in its entirety, including manufacturers, distributors, retailers, and lessors." *Id.* at 629 (citation omitted). Accordingly, the rule could apply to the state providing or facilitating the distribution of drugs from Canada.

Illinois and Massachusetts could also be found liable for breach of implied warranty of merchantability to the extent the states would be deemed to be "merchants" selling goods. Although this is a contract theory, a plaintiff my recover noneconomic damages for personal injury. *Federal Insurance Company v. Village of Westmont*, 649 N.E.2d 986, 989 (Ill. App. 1995). To recover under this theory, a plaintiff must establish a sale of goods, that the seller of the goods is a merchant with respect to goods of that kind, and that the goods were not of merchantable quality. *Garcia, supra*, 613 N.E.2d at 1249; 810 ILCS 5/2-314; *Chapman v. Bernard's Inc.*, 167 F. Supp. 2d 406, 414 (D. Mass. 2001); M.G.L. c. 106, § 2-314. Thus, states that provide Canadian drugs, through a state-run pharmacy for example, could readily be subject to liability for breach of implied warranty of merchantability, for the drugs could be considered "not of merchantable quality" for the same reasons that they could be deemed "unreasonably dangerous" under a strict liability theory.

States could even potentially face liability as "merchants" even if they do not sell the drugs to patients for a charge; whether a defendant is a merchant is a question of fact to be resolved by the factfinder. *Federal Insurance Company, supra,* 649 N.E.2d at 990. Both the Illinois and Massachusetts UCC define a "merchant" as "a person who deals in goods of the kind or otherwise by his occupation holds himself out as having knowledge or skill peculiar to the practices or goods involved in the transaction." 810 ILCS 5/2-104; M.G.L. c. 106, § 2-104. In

Garcia, supra, the court found that a hospital's provision of mitral valves was a "sale," independent of the service of performance of mitral valve replacement surgery, that rendered the hospital subject to liability for breach of implied warranty of merchantability. Thus, if the state's provision of Canadian drugs could be comparably characterized, as, for example, in the dispensing of Canadian drugs at state-sponsored clinics, the state could be held liable for breach of implied warranty.

C. Failure to Warn

A failure to warn of a product's dangerous propensities can give rise to a claim of strict liability, breach of implied warranty of merchantability, or negligence. Under a strict liability theory, the failure to warn of the danger posed by the product renders it unreasonably dangerous. *Schultz v. Hennessy Industries, Inc.*, 584 N.E.2d 235, 242 (Ill. App. 1991). The implied warranty of merchantability includes an assurance that the product is reasonably safe for its ordinary purposes. Consequently, the manufacturer or seller of a product known to be unreasonably dangerous may be obligated to warn those who foreseeably will come in contact with the product. *Cocco v. Deluxe Systems, Inc.*, 516 N.E.2d 1171, 1175 (Mass. App. 1987). Under these two theories, the focus is on the adequacy of the warning, whereas under a negligence theory, the focus is on the particular defendant's knowledge and conduct. *Werckenthein v. Bucher Petrochemical Company*, 618 N.E.2d 902, 908 (Ill. App. 1993). Sellers and distributors, as well as manufacturers, may be subject to a claim for failure to warn. *Cocco, supra*, 516 N.E.2d at 1175; *Schultz, supra*, 584 N.E.2d at 242.

A state that sells, distributes, or otherwise supplies patients with Canadian drugs could potentially be held liable for failure to warn under either a strict liability, breach of implied warranty, or negligence theory. A plaintiff predicating a products liability action upon a failure

to warn must demonstrate that the seller or distributor of the product knew or should have known of the danger that caused his injury. *Schultz, supra*, 584 N.E.2d at 242; see also *Cocco, supra*, 516 N.E.2d at 1175. The purpose of a warning is to apprise people coming into contact with a product of dangers of which they are unaware so that they may take appropriate precautions to protect themselves. *Vallejo v. Mercado*, 580 N.E.2d 655, 662 (Ill. App. 1991).

With respect to Canadian drugs that FDA has specifically identified as potentially problematic, an injured patient could likely show that the state was aware of the danger posed by the drug, and that an appropriate warning would have enabled the patient to take precautions such as seeking monitoring by a health care provider if potency may be an issue, or being alert to possible side effects. An argument for failure to warn would be less strong with respect to other Canadian drugs not singled out by FDA, unless perhaps the plaintiff could argue that the state should have communicated that the Canadian drug might not meet the precise specifications of the FDA-approved drug for which it is intended to substitute and that he would have acted differently had he known.

At least with respect to Canadian drugs FDA has specifically identified as potentially dangerous, a compelling argument for failure to warn could be made with regard to state-run pharmacies. In general, the "learned intermediary" doctrine relieves pharmacists of the duty to warn about possible dangers of prescription drugs, for the patient's physician is deemed to be in the best position to provide any applicable warnings to the patient about the drug. However, courts in Illinois and Massachusetts, as well as in a number of other states, have refused to extend the protections of the learned intermediary doctrine to pharmacists who had specific knowledge of a particular danger to the patient. In *Happel v. Wal-Mart Stores, Inc.*, 737 N.E.2d 650 (Ill. App. 2000), the court held that the pharmacy, which was aware of the patient's

drug allergies, owed a duty to disclose either to the patient or her physician that the prescribed drug was contraindicated. Similarly, in *Cafarelle v. Brockton Oaks CVS, Inc.*, 1996 Mass. Super. LEXIS 421 (Mass. Super. 1996), the court concluded that the pharmacy had a duty to warn the patient and her prescribing physician that the patient may have overused the medication. These cases suggest that where a state-sponsored pharmacy or other state entity dispenses Canadian drugs known to be potentially problematic, it has a duty to warn the patient of the particular harm that users of those drugs might incur.

D. Fraud, Misrepresentation or Unfair Trade Practices

For reasons similar to those discussed above with respect to failure to warn, Illinois and Massachusetts could be found liable for common law fraud or misrepresentation or for violations of those states' unfair trade practices acts if they provide Canadian drugs to patients later injured by them. While the elements of these causes of action vary slightly, they can all be fairly described as requiring a plaintiff to prove that the defendant made a false representation of a material fact with knowledge of its falsity for the purpose of inducing the plaintiff to act thereon, and that the plaintiff relied upon the representation as true and acted upon it to his damage. *See, e.g., Damon v. Sun Company, Inc.*, 87 F.3d 1467, 1471-2 (1st Cir. 1996); *Capiccioni v. Brennan Naperville, Inc.*, 791 N.E.2d 553, 558 (Ill. App. 2003). An omission as well as an affirmative representation may give rise to a claim of fraud, although in Illinois the concealment must have been done with an intent to deceive. *Stewart v. Thrasher*, 610 N.E.2d 799, 803 (Ill. App. 1993). Massachusetts law, however, does not require an intent to deceive. *Damon, supra,* 87 F.3d at 1479.

Applying the foregoing criteria to states supplying Canadian drugs, liability could potentially arise where the states conceal the fact that the drugs provided are from Canada and

are not FDA-approved, or where states make affirmative representations that the Canadian drugs are equivalent to their American counterparts when FDA has made known to them that this is not the case. Recipients of these drugs would have fairly relied upon representations by the state, either in its role as employer or as the holder of police power for the benefit of the public health and welfare. Plaintiffs could potentially show that they acted upon the state's representations to their detriment, and that they would have refused the drugs if they had known of their foreign origin or of the distinctions between the Canadian and American versions.

E. State Collective Bargaining Agreements

Separate and apart from the risk of tort liability, states could face liability for violation of collective bargaining agreements with state employees if the supply of Canadian drugs were considered not to meet the quality or other requirements of the healthcare provisions in a collective bargaining agreement. Further evaluation of this issue would require specific examination of the terms of the agreement in a given state.

* * *

In sum, states that provide or facilitate the distribution of Canadian drugs could potentially face substantial liability under a number of tort and other theories. Cases could be brought by individual plaintiffs, or conceivably by class action, depending on the circumstances. The risk is heightened given that some of the drugs specifically identified by FDA as problematic are fairly widely used, such as Zocor and Glucophage. While the likelihood of plaintiff recovery will vary with each theory and the specific facts regarding the state's involvement in the provision of the drug, FDA's recent announcements of the serious safety concerns presented by Canadian drugs make it more likely that courts or juries would find states liable for harm resulting from such drugs.

Federal Food, Drug, and Cosmetic Act

A. The Statutory Scheme

It is unlawful under the FDCA for anyone to introduce a new drug into interstate commerce that is not covered by an approved new drug application (NDA) or approved abbreviated new drug application (ANDA). FDCA §§ 301(d) & 505(a); 21 U.S.C. §§ 331(d) & 355(a). When a product is introduced into interstate commerce that does not comply fully with an approved application, it is considered an unapproved new drug in violation of section 505 of the FDCA. 21 U.S.C. § 355. It is also misbranded under section 502 of the FDCA. 21 U.S.C. § 352. These basic rules cover importations, since importing is a form of introducing a drug into interstate commerce.

There is no exemption from the requirements of the FDCA for importations of a version of a drug obtained in Canada or another foreign country. *See, e.g.*, FDCA § 801(a); 21 U.S.C. § 381(a) (an article shall be refused admission into the United States if it is "in violation of section 505"). Thus, any importer must demonstrate that the imported product is in full compliance with an approved NDA or ANDA in the United States for the product to be admitted to this country. This includes a demonstration that the imported product was manufactured in a facility covered by an approved application, is labeled in full accordance with the United States approval, and otherwise meets all NDA or ANDA requirements (for example, manufacturing specifications, storage and handling requirements, etc.).

In addition, the reimportation of drug products by anyone other than the original manufacturer is expressly prohibited even if the products are in full compliance with a United States NDA or ANDA. FDCA § 801(d)(1); 21 U.S.C. § 381(d)(1). This prohibition on the

reimportation of products previously manufactured in the United States and exported abroad guards against the entry of counterfeit and adulterated products into this country.

B. Proposed State Imports

Published reports of potential state importation plans contain no assurances that any of the requirements of the FDCA for importations and reimportations will be followed, and it would be virtually impossible as a practical matter for the requirements to be met. For example, even if a drug is manufactured in Canada by the same company that holds the approved NDA in the United States, there is no assurance that the Canadian product is precisely the same as the product manufactured in the United States pursuant to the specifications of the NDA. If the product deviates in any respect from the approved NDA (e.g., in some manufacturing process or specification), it may not be imported. Similarly, it is not clear how any state plan could provide safeguards to prevent the unlawful reimportation of products manufactured in the United States.

States would thus be violating the FDCA if they were to import drugs from Canada or other countries, and would be liable to FDA enforcement action. Potential state liability would exist whether the states were to structure an import program with the states as the actual importer, or with some other entity as the importer. This is because it is a violation of the FDCA not only to introduce a violative drug into interstate commerce, but also to *cause* the introduction of a violated drug into interstate commerce. FDCA § 301; 21 U.S.C. § 331.

If states structure a program so that patients themselves are importing drugs for their personal use, it would still violate the law. FDA has adopted an informal personal importation policy under which it will exercise enforcement discretion and not take action against unlawful importations under certain circumstances. *See* FDA Regulatory Procedures Manual, ch. 9-71. This personal importation policy is commonly misunderstood. The policy

applies only to the importation of small quantities of a drug for personal use *when there is no effective treatment lawfully available in the United States*. It does not apply to importations of foreign versions of drugs approved in the United States, or to reimportations.

If a state (or anyone else) attempts to import products in violation of the FDCA, the Customs Department and FDA are required under section 801(a) of the FDCA to refuse admission of the products at the border 21 U.S.C. §381(a). For products that somehow enter the country illegally, FDA could take enforcement action. For example, FDA might go to court to seek an injunction against violative importations, or seek to seize products that have improperly entered the country.

C. FDA Prouncements

The above legal analysis has been unequivocally confirmed by the FDA. Only a month ago, FDA responded to an inquiry from the State of California in an August 25, 2003 letter making clear that imports of drugs by California from Canada would violate the law. The letter is available on FDA's web site at <http://www.fda.gov/opacom/gonot.html>. Following are verbatim quotes from FDA's letter, which leaves no doubt about the illegality of any state import plan:

- [V]irtually all drugs imported to the United States form Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

- FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a

drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version may also be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

- [W]ith respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

- Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are herby prohibited . . ."). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens through a third-party internet service.

FDA's response to the State of California follows and reinforces equivalent statements FDA has made to private entities involved in Canadian import schemes. For example, on March 21, 2003, FDA issued a warning letter to Rx Depot explaining that shipments of regulated products from Canada to the United States are illegal, and on September 16, 2003 FDA issued a similar warning letter to CanaRx Services. Copies of the warning letters may be found on FDA's web site at <http://www.fda.gov/foi/warning_letters/g3888d.htm> (RxDepot), and <http://www.fda.gov/foi/warning_letters/g4291d.pdf> (CanaRx Services).

FDA has also demonstrated its resolve to stop illegal import programs. After Rx Depot refused to heed FDA's warning letter, FDA directed the United States Department of Justice to bring suit and seek an injunction to shut down the company's import activities. A

press release announcing FDA's actions may be found on the FDA web site at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html>.

Medicaid and Medicare

Because drugs imported by a state from Canada or elsewhere would be unapproved and misbranded under the FDCA, they should not be eligible for federal coverage under the Medicaid or Medicare programs. The Centers for Medicare & Medicaid Services (CMS) has yet to address this issue to our knowledge. However, the plain provisions of the Medicaid law suggest that there would not be federal assistance for illegally imported drugs. The same is true under the Medicare law.

Only FDA-approved drugs and certain other grandfathered products meet the definition of "covered outpatient drug" in the Medicaid drug reimbursement provisions. 42 U.S.C. § 1396r-8(k)(2) (covered outpatient drug means a drug "which is approved for safety and effectiveness as a prescription drug under section 505 (21 U.S.C. 355) . . . of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act (21 U.S.C. 355(j))"). For the reasons explained above, prescription drugs imported from Canada are in almost all cases considered unapproved under the FDCA, and thus do not meet this Medicaid definition. As such, these imported drugs would not be covered by a Medicaid drug rebate agreement (42 U.S.C. § 1396r-8), and it is thus not clear whether or how federal payment would be made. *See, e.g.*, 42 U.S.C. § 1396b(i)(10)(A). In addition, the CMS regulations would prohibit federal payments for any drug not prescribed and dispensed by a licensed physician and pharmacist. 42 C.F.R. § 440.120. This very likely would not be the case for many drugs coming from Canada.

The analysis under Medicare is similar. Section 1862(a)(1) of the Social Security Act contains a general provision prohibiting payments under Medicare Part A or Part B for any expenses incurred for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). For use of a drug or biological to be found "reasonable and necessary," such use also must be safe and effective. Medicare Carriers Manual § 2049.4. CMS considers drugs or biologics approved for marketing by the FDA to be safe and effective when used for indications specified in the drug's labeling, but the drugs at issue here have no FDA approval and thus would not meet the Medicare coverage requirements.

Public Health Considerations

Compelling public health and public policy considerations exist for FDA and others to take action against illegal import programs. The laws governing the importation and reimportation of prescription drugs are carefully crafted to protect patients from illegal, contaminated, and counterfeit drugs. Any failure to enforce these laws fully and faithfully risks exposing American consumers to very real dangers. Outright counterfeit products could be imported, masquerading as bona fide United States products. Alternatively, patients might receive drugs that have been manufactured at unregistered and uninspected facilities, or that have been distributed by wholesalers without compliance with the pedigree requirements of section 503(e)(1) of the FDCA. 21 U.S.C. § 353(e)(1). These drugs may have been made and stored according to unvalidated procedures and specifications, and may not comply with current good manufacturing practices (cGMPs). Any such deviations from the rigorous standards contained in an approved NDA or ANDA could produce adulterated products that are impotent, subpotent, superpotent, or even toxic.

If FDA or other agencies unilaterally relax the existing import laws, and make an exception for state programs, it would establish a dangerous precedent. Similar import programs might be established elsewhere to bring drugs in from Canada, Mexico, or other countries. FDA would be hard-pressed to prevent this expansion after effectively blessing a state program through inaction. The ultimate result could be the creation of a new and essentially unregulated drug distribution channel that could be used to circumvent the basic protections that exist under United States law to protect the safety, effectiveness, and integrity of the drug supply.

Michael S. Labson
Miriam J. Guggenheim

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 25 2003

Mr. Gregory Gonot
Deputy Attorney General
State of California
Department of Justice
1300 I Street
Sacramento, California 95814

Re: Opinion No. 03-601

Dear Mr. Gonot:

I write in response to the letter of July 28, 2003, that your colleague, Rodney O. Lilyquist, sent the United States Food and Drug Administration (FDA) regarding the importation of prescription drugs from Canada into the State of California.

I. QUESTIONS PRESENTED

Mr. Lilyquist's letter asks nine separate questions about the potential liability associated with importing prescription drugs from Canada. All nine of the questions relate to one of three basic issues:

- Questions 1 – 6 query whether it is legal to purchase drugs from Canada and import them into the State of California.

- Questions 7 – 8 query whether the federal law in this area preempts the State of California (or a county or city within the state) from enacting a law that would legalize the importation of prescription drugs from Canada.

- Question 9 queries whether public pension funds such as CALPERS or CALSTRS can negotiate for Canadian prescription drug prices for their members.

II. SHORT ANSWER

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in

Canada and ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it had not been appropriately refrigerated when shipped back into the country. The failure to refrigerate insulin promotes the degradation of the drug and renders it less effective. Unfortunately, however, the failure to refrigerate the product may not change its appearance, so American consumers may have no way of knowing their insulin has been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of California (including any state, county, or city program, any public pension, or any Indian Reservation) were to import prescription drugs into the State of California from Canada, it would violate FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts the State of California (and any city or county within the state) from passing conflicting legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

III. ANALYSIS

1. Questions 1 – 6: The importation of prescription drugs from Canada

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.[1]

First, virtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are

[1] We will limit our discussion to drugs imported from Canada because your request is so limited. The legal analysis is the same for drugs imported from any foreign country.

not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited..."). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens through a third-party internet service. [2]

With respect to questions 4 and 5 of Mr. Lilyquist's letter, please note that the preceding analysis applies also in the case of sovereign Indian nations located in the State of California. FDA considers Indian Reservations to be possessions of the United States within the meaning of 21 U.S.C. § 321(a)(2). Accordingly, FDA asserts complete jurisdiction over products within the purview of the FFDCA that are imported, purchased, or sold by an Indian reservation. *See FPC v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960); *United States v.*

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[2] The issue of whether persons may broker the sale of Canadian drugs through an internet operation is discussed more fully in Warning Letters that FDA sent to Rx Depot (March 21, 2003) and CanadianDiscountDrugs (June 30, 2003). A copy of those letters is enclosed and can also be obtained through FDA's website at www.fda.gov. They are particularly responsive to question number 6 in Mr. Lilyquist's letter, which queries whether an Indian nation may sell Canadian prescription drugs through a website to other residents of California.

Baker, 63 F.3d 1478, 1484 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 824 (1996); *United States v. Funmaker*, 10 F.3d 1327, 1330 (7th Cir. 1993); *EEOC v. Fond du Lac Heavy Equipment and Construction Co.*, 986 F.2d 246, 248 (8th Cir. 1993).

With respect to question 6 of Mr. Lilyquist's letter, please note also that the preceding analysis applies to persons who import drugs into the United States on their person or on a bus. In those cases where the FFDCA prohibits the importation of a prescription drug, it makes no legal difference whether that drug has been imported through the mails, delivered by a private shipping company, or carried across the border on one's person. *See* 21 U.S.C. §§ 331 and 381.

FDA's Personal Importation Policy

There has been some recent confusion in the press about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. Recent advertisements in certain domestic newspapers and magazines have implied that Congress has made the personal importation of drugs a legal practice. Other advertisements and certain Internet sites have stated that personal importation of up to a 90-day supply of prescription medications is legal. Neither of these messages is true.

The Personal Importation policy is used to help guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. *See* FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities; it does not change the law.

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C.

§§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A).

Those who can be found civilly and criminally liable include all who cause a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the FFDCA, or conspire to violate the FFDCA, can also be found criminally liable under 18 U.S.C. §§ 2 and 371.

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad.[3] With respect to question 6 in Mr. Lilyquist's letter, please note that, as a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Please also note that, under current California law, state-sponsored importation of drugs from Canada for use in the state's Medi-Cal program may violate the statutory and regulatory requirements for this program. *See* West's Ann. Cal. Welf. & Inst. Code, § 14100, *et. seq*; Cal. Admin. Code tit. 22, § 50000, *et. seq*. For example, the importation of drugs from Canada may violate the Prudent Purchase of Drugs Program, 22 CCR § 51513.6, because the drug products are not "handled in accordance with the provisions of applicable federal and state law." In addition, we question whether the state would be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law. FDA has not researched and does not here advise you of any tort liability that may arise under state law, but we cite the issue as a possible concern.

2. Questions 7 and 8: Federal preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

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[3] *See, e.g.*, the Warning Letter that FDA sent to Rx Depot on March 21, 2003, the Warning Letter that FDA sent to CanadianDiscountDrugs on June 30, 2003, and the letter that FDA sent the Kullman Firm of New Orleans, Louisiana on February 12, 2003. A copy of the Kullman letter has also been enclosed for your review.

The Supreme Court has held:

> under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances; first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984) (quotation marks and citations omitted); *see also English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams*, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia*, Congress has intended to occupy a field of regulation comprehensively (termed "occupation of the field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). *See English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Occupying the field

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." (emphasis added) *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 US 707, 713 (1985), *quoting Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly,

Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. If the state of California were to enact a law that contravened the scheme, there is no question that the result would be inconsistent with the plain objectives of the FFDCA.

Implied conflict preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.*, 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of certain drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of California to pass legislation conflicting with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

3. Question 9: Public Pension Funds

As noted above, the import prohibitions in the FFDCA apply to both public and private entities. *See* 21 U.S.C. §§ 321(e) and 331. Thus, a public pension fund would be subject to the same liability as a private citizen for a violation of the import provisions of the FFDCA.

I. CONCLUSION

I hope that the preceding discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many

drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that would legalize imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

Nevertheless, we are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products and generally no more expensive in the United States than the generic drugs sold elsewhere in the industrialized world. The Administration is also working with the Congress on landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

Encl: FDA letter to the Kullman Firm (February 12, 2003)
FDA Warning Letter to Rx Depot (March 21, 2003)
FDA Warning Letter to CanadianDiscountDrugs (June 20, 2003)

McKesson Corporation
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San Francisco, CA 94104

[redacted]

McKESSON
Empowering Healthcare

March 31, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Task Force on Importation (21 CFR Chapter I)
[Docket No. 2004N-0115]

Dear Sir or Madam:

On behalf of McKesson Corporation, we are pleased to submit comments to the U.S. Department of Health and Human Services for the Task Force on Importation. McKesson commends the agency for undertaking a study of drug importation and we appreciate the opportunity to share our perspective.

McKesson is the largest pharmaceutical supply management and health information technology company in the world. We are also the largest pharmaceutical distributor in North America, through our ownership of McKesson Canada, the leading wholesale distributor in Canada, and our equity holding in Nadro, a leading distributor in Mexico. We provide a broad array of products and services to over 5,000 hospitals, 35,000 physician practices, 10,000 extended care facilities, 700 home care agencies, 25,000 retail pharmacies, 600 payors, 450 pharmaceutical manufacturers and 2,000 medical-surgical manufacturers. McKesson also repackages over 1.5 billion doses of drugs annually and provides analytical testing services in support of these operations.

For the past 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 16 corporation, McKesson delivers vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in every health care setting. We understand the critical importance of medication safety and the need to protect the integrity of the pharmaceutical supply chain. McKesson has strict policies and procedures in place that both ensure the safety of the products we distribute and exceed the safety requirements of the countries in which we operate. We source 99.5% of our products in the U.S. and 100% of our products in Canada directly from the manufacturers.

We also understand that many people do not have adequate access to the pharmaceuticals they need. As the administrator of the Together Rx^{TM} card, McKesson has actively promoted a safe and workable solution to high drug prices for low-income seniors. As of

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March 28, 2004, over 1.2 million seniors are enrolled in the Together Rx™ drug savings card and have obtained demonstrated savings of over $318 million.

McKesson has also been an industry leader in the development and application of technology in health care supply management, in pharmacy automation, and in bedside barcode scanning of pharmaceuticals to assure patient safety. We were the first drug distributor to fully automate our distribution process by implementing radio frequency and scanning technology throughout our entire warehouse and distribution network. Today, we are engaged in a joint innovative effort with Wal-Mart to beta-test RFID (radio frequency identification) technology for use in tracking inventory and assuring product safety.

Evaluation of Drug Importation

Our long history and expertise in the pharmaceutical distribution business in both the U.S. and in Canada, combined with our steadfast commitment to a safe and cost effective drug supply, provide us with unique insights on many of the questions that have been raised concerning the importation of pharmaceutical products.

McKesson has serious concerns that a broad-based importation system may not assure both product safety and cost savings to the American consumer. However, it is possible that the safety and cost savings issues could be addressed through a narrower "closed distribution" system. Under such a system, pharmaceutical distributors with the appropriate technology, experience, and distribution networks on both sides of the border could safely transfer products between their distribution centers in Canada and their distribution centers in the U.S. To assure safety, these distributors must source 100% of their products directly from the manufacturers. Clearly, such a system would depend on the availability of product in Canada, the cooperation of key members of the supply chain, and the development of an allocation system to ensure equitable distribution to the American public.

It is important to recognize that U.S. demand for lower-priced pharmaceuticals will always exceed the available supply from Canada or from any other exporting country. The U.S. pharmaceutical market is the largest in the world, amounting to almost half of the world's pharmaceutical spending. In comparison, the Canadian market is less than $1/20^{th}$ of the size of the U.S. market. This imbalance in demand will require an allocation system to ensure equitable distribution of the available imported pharmaceutical products. McKesson recognizes that any allocation policy will be highly controversial and will require government intervention.

McKesson Corporation
One Post Street
San Francisco, CA 94104

If an importation system is devised, we believe there are significant challenges that may make it difficult to safely provide an adequate supply of lower priced product. Addressing these challenges will add costs that could negate any potential savings. To ensure a secure and cost-effective supply chain, the Task Force must address the following issues of product safety and costs.

Safety

The preservation of a safe pharmaceutical supply chain is essential. There are several factors affecting the safety of imported products that merit particular attention.

1) Regulatory Oversight

As we have previously noted, demand in the U.S. will far outstrip the available foreign supply of pharmaceuticals. This disproportionate demand may create financial incentives for legitimate and illegitimate operators to seek alternate sources for prescription drugs and increases the threat of a gray market for vital medicines.

While Canada has strict policies in place to ensure the safety of pharmaceuticals for its citizens, the Canadian government has stated that it cannot guarantee the safety of drugs shipped to the U.S. At the same time, the U.S. lacks the resources to adequately monitor products shipped directly to patients over the border. Actual or alleged trans-shipment of product through Canada could result in the development of a gray market that is difficult to monitor. Adequate regulations and supporting resources are needed to prevent the shipment, through Canada, of pharmaceutical products that are improperly stored or handled, sub-potent, expired, adulterated, or counterfeit. Additionally, the institution and enforcement of severe criminal penalties are needed to deter those who knowingly distribute compromised pharmaceutical products.

Internet and international mail order pharmacies provide another channel for the importation of foreign product which is unregulated by U.S. authorities. McKesson believes that the lack of international, federal and state regulations has left consumers vulnerable to unsafe drugs. We have previously recommended that the FDA ban domestic and international prescription drug sales via the Internet unless those transactions and businesses are held to the same regulatory and licensing standards established by the Prescription Drug Marketing Act, state Boards of Pharmacy, and Departments of Health, and currently applied to U.S. distributors and pharmacies.

2) Product Testing, Packaging and Labeling

Appropriate testing of imported products may be required to ensure safety and potency. While resources exist at McKesson and elsewhere to test imported products, questions

remain as to the parameters of the testing, ability to access patented information to assure adequate testing, liability and costs associated with the testing.

Under current federal regulation, most foreign labels and packages do not comply with the Food, Drug & Cosmetic Act, as required for legal sale in the U.S. Lack of barcoding or NDC numbers on foreign products may require additional repackaging to enable rapid and efficient distribution of these products from wholesalers to pharmacists to patients. Country of origin labeling and language requirements for package inserts must also be considered. Should patient or product safety concerns necessitate relabeling or repackaging of imported products, additional costs will ensue.

3) Inventory Tracking

McKesson has been an advocate and leader in the adoption of technology to track and trace products through the supply chain. The use of electronic technology to track products from foreign countries would help to ensure that products are sourced in FDA-approved facilities and shipped through legitimate wholesale channels prior to sale in the U.S. The effective implementation of such a system for importation, however, poses significant challenges. Pharmaceutical manufacturers must agree to tag products globally at the time of manufacture, and approved foreign intermediaries must adopt the electronic reading technology. Despite wide spread support for such technology, harmonized standards to facilitate broad adoption of these technologies are still under development.

Tracking products without such electronic documentation could compromise the integrity and the efficiencies of the pharmaceutical distribution network. Paper pedigrees that are designed to document the source of the product and its movement through the distribution chain are subject to counterfeiting. McKesson has previously submitted comments to the FDA in opposition to the use of paper pedigrees, which can be easily forged and which cannot be effectively transmitted through our currently paperless and virtually automated distribution channel.

4) Recall Mechanism

Product recalls are currently initiated by the manufacturer and facilitated by wholesalers and pharmacies. Most recalls are national in scope, not global. It will be necessary to establish a process for recalls in the absence of a single governing body that has jurisdiction on both sides of the border. In order to execute a recall of foreign products, systems will have to be developed and instituted to monitor and track foreign-sourced products. It is also likely that segregated inventories of foreign-sourced and domestic-sourced product will have to be maintained at the wholesaler and pharmacy level. Questions will arise as to responsibility for initiating and overseeing the process and subsequent liability for such recalls.

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Costs

Ensuring the safety of the supply chain will add significant costs to imported product. Regulatory oversight, testing, repackaging/relabeling, tracking and recall mechanisms will reduce any available cost savings. In addition, other factors could further increase the cost of importation and reduce savings to U.S. consumers:

1) Proper Importation Documentation
Well executed importation has associated costs, including import/export licenses, customs broker fees, tariffs, bonds, and documentation fees.

2) Product Pricing
The economic principles of supply and demand, as well as currency fluctuations, will also impact any cost savings available through importation. In Canada, national and provincial bodies currently set and regulate prices for pharmaceutical products. These regulations apply only to products dispensed in Canada. Canadian price controls exist for Canadian citizens, not for the export market. In a legalized importation environment between the U.S. and Canada, we would expect the prices at which Canadian entities sell to the U.S. to rise as demand exceeds available supply. In fact, drugs exported from Canada are already sold at prices above domestic Canadian prices.

3) Generic Substitution
Generic pharmaceuticals are generally less expensive in the U.S. than in Canada and account for approximately 45% of the unit volume of drugs consumed in the U.S. American pharmacies today actively promote generic substitution. Under legalized importation, consumers may ultimately pay more to import a branded product than they would for a domestic generic product that is readily available.

4) Reimbursement
Reimbursement for pharmaceutical products by third party payors will need to be thoughtfully addressed in any importation system. Pharmacies and payors will need systems to track different channels of product acquisition in order to accurately reflect their average acquisition costs, upon which reimbursements by Medicaid are based. Foreign-sourced drugs will not have NDC numbers, which are the basis for most pharmacy management and reimbursement systems. Furthermore, it remains unclear as to what extent health insurers and government payors, including CMS, would reimburse pharmacies and patients for foreign-sourced products. Administrative complexities, and resulting costs, would increase as insurers implement systems to track and reimburse foreign-sourced products and provide adequate medication therapy management, drug utilization review, safety and counseling efforts for these products.

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5) Liability

The importation of pharmaceutical products is also likely to entail the assumption of additional liability. Without regulations governing liability for imported product, it is unclear who (e.g. manufacturers, importers, government, payors) would bear liability for any adverse drug events associated with products sold outside their country of intended use. Additionally, since September 11, 2001, security concerns coupled with the rising cost of insurance have made it increasingly difficult for companies to attain adequate liability coverage. Liability insurance covering imported products is likely to be costly, thereby further reducing available cost savings.

Conclusion

Given our unique capabilities in Canada and the U.S., we stand ready to share our expertise to help the Task Force better understand safety and cost issues associated with drug importation. McKesson is committed to removing unnecessary costs from the health care system as we ensure the timely delivery of safe, cost-effective products. We remain concerned about the safety, cost and allocation issues which we believe could present significant barriers to the successful implementation of any importation system.

McKesson appreciates the opportunity to provide comments and recommendations based on our distribution experience within North America and the strict policies and procedures we have implemented to assure product safety. We applaud the FDA's commitment to providing a safe channel for lower cost drugs, and look forward to ongoing collaboration and cooperation to ensuring the safety, efficiency and effectiveness of the pharmaceutical distribution system.

Sincerely,

Ann Richardson Berkey
Vice President, Public Affairs

Agenda Item B

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: June 14, 2004**

From: **Patricia F. Harris**
Executive Officer

Subject: **Public Disclosure of Citations and Fines**

At its last meeting, the Board of Pharmacy revised its disclosure policy. During the discussion, licensees expressed concern regarding the disclosure of administrative citations. Administrative citations are not considered discipline of a license. However, they do represent a substantiated resolution of an investigation that is disclosed to the public.

To address the concerns of licensees, the following language has been added to the citations to advise the licensee: "If a hearing is not requested to contest the citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For cases where no fine has been issued the following will be provided:

"No fine has been assessed with this citation and no proof of abatement has been ordered. If no hearing is requested to contest the citation, the right to contest the citation has been waived. If the citation is not contested, the citation shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For disclosure to the public, the following language is being proposed to address licensees' concerns:

The issuance of a letter of admonishment and/or a citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The final administrative action including payment of a fine does not constitute an admission of the violation(s) charged and is considered satisfactory resolution of the matter. (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

Agenda Item C

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: June 14, 2004**

From: **Patricia F. Harris**
Executive Officer

Subject: **Biometric Fingerprint Recognition Technology and Request for a Waiver**

Rite Aid Corporation is requesting a waiver of CCR, title 16, sections 1793.3 and 1793.7 to accept Rite Aid's biometric fingerprint recognition technology as a means of complying with the requirement that a pharmacist must sign the prescription label as a means of verifying a prescription that a pharmacy technician has prepared.

If the board decided that the use of biometric fingerprint technology is a viable alternative to the pharmacist's signature on the prescription label, a legislative change would be required. The requirement to sign the prescription label is found in Business and Professions Code section 4115(f).

Agenda Item D

Agenda Item E

FAX

To: Patricia Harris
Pharmacy Board

Fax: (916) 327-6308

From: Linda Morris
Manager, Licensing Operations Section
Medical Board of California

Attached please find a copy of the letter mailed February 9, 2004 to all retired physicians notifying them of the change to retired status and voluntary status and the options that are available to them. This is the result of SP 1077 and the implementation date is 7/1/04 for the retired status and 1/1/04 for the voluntary status.

The letter dated 6/2/04 was mailed to the Medical Societies in California and all hospitals to make them aware of these changes.

This is to notify you of these changes. We feel that the pharmacists should be notified to assure retired doctors do not write prescriptions on or after 7/1/04 since they will no longer be able to practice medicine.

STATE OF CALIFORNIA -- STATE AND CONSUMER SERVICES AGENCY ARNOLD SCHWARZENEGGER, *Governor*

State of California Department of Consumer Affairs

MEDICAL BOARD OF CALIFORNIA
LICENSING PROGRAM
1428 Howe Avenue, Suite 56
Sacramento, CA 95825-3236
Telephone: (916) 263-2417 Fax: (916) 263-2567
Website: www.caldocinfo.ca.gov

June 2, 2004

To Whom it May Concern:

RE: Notice of Changes to Retired Status as a result of SB 1077

This is to advise that on and after July 1, 2004, a physician who is in retired status will no longer be eligible to practice medicine. Senate Bill 1077 (Chapter 607, Statutes of 2003) states that physicians and surgeons who hold a retired license will still be exempt from payment of the renewal fee and the continuing medical education (CME) requirements, however, the holder of a retired license may not engage in the practice of medicine.

Additionally, this law removes some of the restrictions that affect physicians who are in voluntary service status. Effective January 1, 2004, a physician whose license is in voluntary service status is no longer limited by the requirement to practice solely in a not-for-profit agency in an underserved area of this state.

This is to notify you that physicians and surgeons who are currently in retired status and wish to receive compensation for practicing medicine or continue to write prescriptions, will need to request that their license be restored to full active status. If physicians are providing voluntary, unpaid service, they must apply for a voluntary service license. In order to continue practicing without interruption physicians must notify the Medical Board of any desired change prior to July 1, 2004.

I hope this information is helpful in explaining the recent changes to the retired and voluntary status'. If you have any questions regarding the above information, do not hesitate to contact the Medical Board's Consumer Information Unit at (916) 263-2382.

Sincerely,

Joyce E. Hadnot
Acting Chief, Licensing Program

STATE OF CALIFORNIA -- STATE AND CONSUMER SERVICES AGENCY ARNOLD SCHWARZENEGGER, *Governor*

Consumer Affairs

MEDICAL BOARD OF CALIFORNIA
EXECUTIVE OFFICE
1430 Howe Avenue, Suite 92
Sacramento, CA 95825-3236
Telephone: (916) 263-2389 Fax: (916) 263-2387
Website: www.medbd.ca.gov

February 9, 2004

Re: Notice of Changes to Retired Status as a result of SB 1077

Dear Doctor:

This is to advise you that on and after July 1, 2004, a physician who is in retired status will no longer be eligible to practice medicine. Senate Bill 1077 (Chapter 607, Statutes of 2003) states that physicians and surgeons who hold a retired license will still be exempt from payment of the renewal fee and the continuing medical education (CME) requirements, however, the holder of a retired license may not engage in the practice of medicine.

Additionally, this law removes some of the restrictions that affect physicians who are in voluntary service status. Effective January 1, 2004, a physician whose license is in voluntary service status is no longer limited by the requirement to practice solely in a not-for-profit agency in an underserved area of this state.

This is to notify you that if you are currently in retired status and wish to receive compensation for practicing medicine or continue to write prescriptions, you will need to request a change to your license status. Should you wish to remain in retired status no action is required. In order to continue your practice eligibility without interruption, you will need to notify us of any desired change to your licensure status no later than June 1, 2004. Listed below are the status options for your consideration. For your convenience we have enclosed the applications required for the various options listed below.

- **Voluntary Service Status.** This status allows the renewal fee to be waived when the license is renewed for the sole purpose of providing voluntary, unpaid service. Compliance with CME will still be required unless a CME waiver is separately granted. To request this status please complete the attached application for "Voluntary Service", the "Financial Interest and CME Statement" and return them with your current retired wallet license. A new wallet license will be issued to you that identifies the new license status.

- **Active License Status.** This status allows full and unrestricted practice. Compliance with CME will be required. To restore your license to active status, the biennial license renewal fee of $600.00 will be required along with the application to "Restore to Active Status", certification of CME, and the "Financial Interest Statement". Please return them with the $600.00 biennial renewal fee and your current wallet license. A new wallet license will be issued to you that identifies the new license status.

- **New Retired Status.** The holder of this license may no longer engage in the practice of medicine. A licensee who holds a retired license will still be exempt from payment of the renewal fee and from the continuing medical education requirements. A physician who wishes to remain in retired status will not be required to take any action at this time. On July 1, 2004, all physicians who remain in retired status will be issued a new wallet license by the Board which will reflect "Retired - No Practice Allowed".

- **Voluntary Surrender.** The license may be canceled at the licensee's request. That license will not be eligible to be renewed or restored. If you later decide to become licensed, you will be required to apply for a new license and will be subject to the requirements in effect at that time.

After choosing one of the above options please submit the required forms and fees (if required) for that option to the Medical Board of California, Licensing Operations Section, 1428 Howe Avenue, Suite 54, Sacramento, CA, 95825. Please check each required form to be sure it has been completed correctly and you have signed in all boxes requiring signature, attached any required fees, and you have included your current wallet license. Applications must be received by the Medical Board no later than June 1, 2004 in order to be processed before July 1, 2004. Please be aware the renewal cycle in which your license expires is based upon your date of birth . Those persons choosing to change to active or voluntary service status, depending upon date of birth, may have a renewal period of less than 24 months.

I hope the above information is helpful in explaining the recent changes to the retired status as well as options that are currently available to you. If you have any questions regarding the above information, or about your eligibility in a license status, do not hesitate to contact the Medical Board's Consumer Information Unit at (916) 263-2382.

Sincerely,

for Jehadnot

Ron Joseph
Executive Director

Enclosures

Agenda Item F

400 R Street, Suite 4070, Sacramento, California 95814
Phone (916) 445-5014 Fax (916) 327-6308
www.pharmacy.ca.gov

DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Senate Bill 151 Questions and Answers - DRAFT

TRIPLICATES OUT – NEW TAMPER-RESISTANT SECURITY PRESCRIPTIONS IN

Q What are tamper-resistant security prescription forms?

A Effective July 1, 2004, the triplicate prescription form is being replaced with a new tamper-resistant security prescription form that prescribers must purchase from designated security printers that has been approved by the Board of Pharmacy and the Department of Justice. To obtain a list of ***approved security printers***, visit the Board of Pharmacy website at http://www.pharmacy.ca.gov/app_sec_printers.htm. Choose an approved security printer from the list and phone, fax or visit their webpage to place an order for the new tamper-resistant security prescription forms. Prices vary.

Q What is an *approved* "security printer"?

A A *security printer* is a printing company that has applied to and been *approved* by the Board of Pharmacy and the Department of Justice to produce the new tamper-resistant security prescription forms for use by authorized California prescribers beginning July 1, 2004. Visit our website at http://www.pharmacy.ca.gov/app_sec_printers.htm for a list of approved security printers. If a company is not listed on the Board of Pharmacy website, it is not an approved security printer and cannot legally print the new tamper-resistant security prescription forms. Prices vary.

Q How do I find an approved security printer to order the new tamper-resistant security prescription forms?

A Visit the Board of Pharmacy website at http://www.pharmacy.ca.gov/app_sec_printers.htm, choose a printing company from the list of approved security printers, and contact them directly to order the new prescription forms. Please have a copy of the prescriber's state license and DEA registration available when you order. If a company is not listed on the Board of Pharmacy website, it is not an approved security printer and cannot legally print the new tamper-resistant security prescription forms. Prices vary.

Q Can a prescriber use up his current supply of triplicate forms before using the new tamper-resistant security prescription forms?

400 R Street, Suite 4070, Sacramento, California 95814
Phone (916) 445-5014 Fax (916) 327-6308
www.pharmacy.ca.gov

DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

A Yes, beginning July 1, 2004, a prescriber can use either the new tamper-resistant security prescription or the triplicate prescription for Schedule II controlled substance prescriptions, and may do so until December 31, 2004. Effective January 1, 2005, the new tamper-resistant security prescription form must be used for **all** ***written*** controlled substance prescriptions. The Department of Justice will no longer accept orders for triplicate forms after June 30, 2004.

Q Are triplicate prescription forms valid after July 1, 2004?

A Yes, triplicate prescription forms are valid until December 31, 2004. Prescribers may order triplicate prescription forms in any quantity up until June 30, 2004, by calling the Bureau of Narcotic Enforcement, Triplicate Prescription Program at (916) 227-4050. Effective July 1, 2004, triplicate prescription forms are being replaced with a new tamper resistant security prescription form that prescribers must order from a "security printer" *approved* by the Board of Pharmacy and the Department of Justice. Prescribers can use either the triplicate form or the new tamper resistant security prescription form during the phase in period of July 1, 2004 through December 31, 2004 for Schedule II prescriptions. After January 1, 2005, all controlled substance prescriptions must be on the new form. Visit our website at http://www.pharmacy.ca.gov/app_sec_printers.htm to obtain a list of approved security printers that you call directly to place an order. Prices vary.

Q After January 1, 2005, what do prescribers do with their old triplicate forms?

A Please return them to the Department of Justice, Bureau of Narcotic Enforcement, Triplicate Prescription Program, P.O. Box 903327, Sacramento, California 95816. For more information, please call (916) 227-4050.

Q How long is a controlled substance prescription valid?

A Effective January 1, 2004, prescriptions for **all** Schedules (II thru V) of controlled substances are valid for 6 months from the date written. Pharmacists should disregard the 14-day restriction currently on the triplicate form.

Q Can prescribers write a prescription for a non-controlled substance on the new tamper-resistant security prescription forms?

A Yes, effective July 1, 2004, all written prescriptions can be on the new form, both controlled and non-controlled substances.

Q Can a prescriber write a non-controlled and a controlled substance prescription on one tamper-resistant security prescription form?

A Yes, as long as the prescription states "prescription is void if the number of drugs prescribed is not noted" and the total number of drugs are written in the designated space on the prescription form.

Q Can a prescription include more than one controlled substance (Schedules II thru V) on the same tamper-resistant security prescription form?

A Yes, as long as the prescription states "prescription is void if the number of drugs prescribed is not noted" and the total number of drugs is written in the designated space on the prescription form.

Q Can a Schedule II controlled substance and a Schedule III controlled substance be written on the same tamper-resistant security prescription form?

A Yes, as long as the prescription states "prescription is void if the number of drugs prescribed is not noted" and the total number of drugs are written in the designated space on the prescription form.

Q What replaces a skilled nursing facility/hospice pharmacy generated triplicate prescription form (SNF form)?

A Effective July 1, 2004, the pharmacy can use a form of its own design.

Q Can a California pharmacy fill a prescription for a Schedule II controlled substance that was written by an out-of-state prescriber for an out-of-state patient? What about Schedule III thru V controlled substances?

A Yes, if the prescription conforms to the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed. **Note**: The prescription is to be delivered to the patient in the other state. Prescriptions for Schedule II controlled substances must be reported to CURES and effective January 1, 2005, prescriptions for both Schedule II and III must be reported to CURES. The best way to handle out-of-state prescriptions for Schedule III thru V controlled substances is to have the prescriber phone or fax in the order to the pharmacy.

Q Can a California pharmacy fill a prescription for a controlled substance written by an out-of-state Nurse Practitioner?

A Yes, if the nurse practitioner has a DEA registration authorizing him or her to write the controlled substance prescription.

Q Can a California pharmacy fill a prescription from an out of state prescriber for a patient in California?

A Business and Professions Code section 4005(b) permits the board to adopt regulations that permits dispensing of drugs or devices in emergency situations, or when a prescription is written by a person licensed to prescribe in another state, where the person, if licensed in California in the same license classification, would under California law, be permitted to prescribe drugs and devices, and where the pharmacist has interviewed the patient to determine authenticity of the prescription. California Code of Regulations section 1717(d) allows written and oral prescriptions from out-of-state prescribers in accordance with this section. The pharmacist should use his or her best professional judgment when filling out-of-state prescriptions.

Q How does the prescriber mark the quantity check off boxes on the new tamper-resistant security prescription form when writing a prescription for multiple drugs on one prescription?

A The prescriber should check the box next to the total quantity for all prescriptions combined.

Q Is a federal controlled substance registration number the same thing as a DEA Registration number?

A Yes

Q How does a pharmacist know that a prescriber has the authority to write controlled substance prescriptions using the new security prescription form? The Department of Justice verifies that a prescriber can write Schedule II controlled prescriptions prior to filling an order for triplicate forms.

A Pursuant to Health and Safety Code section 11161.5 et seq., the security printer is required to verify that the prescriber ordering the new tamper-resistant security prescription forms holds a valid license and has the authority to write controlled substance prescriptions (any or all Schedules II – V). If you are concerned that a prescriber is not authorized to specifically write a Schedule II controlled substance prescription, the board recommends asking the prescriber to provide you with a copy of his or her DEA registration which lists the schedules of controlled substances the he or she is authorized to prescribe.

Q After January 1, 2005, can a prescriber write a Schedule III thru V prescription for a terminally ill patient on a regular plain prescription form as long as the prescriber references the 11159.2 exemption?

A No, there is no terminally ill exemption for Schedule III thru V controlled substances. These prescriptions must be written on the new tamper-resistant security prescription. The intent of the exemption was to make it easier for terminally ill patients to obtain strong pain medication. The exemption applies to Schedule II drugs, which can be written on a plain prescription form with reference to the 11159.2 exemption. As an alternative, prescribers can call in or fax prescriptions for Schedule III thru V drugs.

Q It appears that a pharmacist's ability to correct an error or errors on a Schedule II prescription is eliminated on January 1, 2005, is that true?

A No, current law (Health and Safety Code section 11164(a)(5) as of July 1, 2004, allows a pharmacist to fill a Schedule II prescriptions containing error(s) if the pharmacist notifies the prescriber of the error(s) and the prescriber approves any correction; the prescriber shall fax or mail a corrected prescription to the pharmacist within 7 days of the drug being dispensed. As of January 1, 2005, a Schedule II prescription containing error(s) shall be handled as any other prescription that is uncertain, unclear, and/or ambiguous. The prescriber shall be contacted to obtain the information to validate the prescription (California Code of Regulations section 1761(a)).

Q Do prescriptions for all controlled substances have to be entirely in the prescriber's handwriting?

A No, the prescriber must only sign and date the controlled substance prescriptions in ink.

Q Can a pharmacy technician authenticate a controlled substance prescription? For example, verify a stamped signature, verify a prescription that appears to be a copy, verify a typewritten date on a controlled substance, or verify the source of the new fax-in prescription.

A No. Business and Professions Code section 4115(a) states that a technician may "perform packaging, manipulative, repetitive, or other nondescretionary tasks." California Code of Regulations section 1793.2 defines this more clearly as "Nondiscretionary tasks as used in Business and Professions Code section 4115 which includes:

- removing the drug or drugs from stock;
- counting, pouring, or mixing pharmaceuticals;
- placing the product into a container; or
- packaging and repackaging

Q Can the new tamper-resistant security prescription forms be preprinted with more than one prescriber; for example, a group practice setting?

A Yes. The forms may include a check box or some other means to identify the specific prescriber's name, category of licensure, state license number, and DEA number who has written the prescription.

Q If a prescriber has several offices, can he or she order the new tamper-resistant security prescription forms preprinted with all of the addresses listed?

A Yes, multiple addresses for one prescriber may be listed on the form. The forms may include a check box or some other means to identify the specific address where the patient was seen.

Q Can a prescriber purchase stock prescription blanks for a laser or dot matrix printer that comes with all of the security features except for the preprinted prescriber name, category of licensure, address, DEA number and state license number.

A No, the preprinted prescriber information is one of the security features and therefore, must be preprinted by the approved security printer. However, an approved security printer could offer for sale tamper-resistant security prescription blanks designed for laser or dot matrix printers as long as they are preprinted with the prescriber information before shipping to the prescriber. The prescriber could then send the patient and prescription information electronically to print on the laser prescription blank. The prescriber must the sign and date the prescription in ink.

ORAL AND FAXED PRESCRIPTIONS

Important Note: Due to a security feature on the new tamper-resistant prescription forms that prints "void" across the face of the prescription when faxed or copied, prescribers are encouraged to use a regular prescription form when faxing prescriptions.

Q Can a prescriber call in or send a fax to a pharmacy for a Schedule II controlled substance?

A No, with two exceptions. A licensed skilled nursing facility, an intermediate care facility, home health agency or hospice program can call in an order or send a fax prescription for Schedule II through V controlled substances. The pharmacist must reduce the prescription to hard copy on a form of the pharmacy's own design, and sign and date the prescription in ink. The other exception is for an emergency situation where loss of life or intense suffering may occur by not filling the prescription. Pharmacists must reduce the prescription to hard copy form, and sign and date. The prescriber must, within 7 days, provide a written prescription on the new security prescription form (or triplicate form between July 1, 2004 and December 31, 2004.)

Q Can a prescriber call in or send a fax prescription for Schedules III – V controlled substances?

A Yes. The pharmacist must reduce the prescription to hard copy form, and sign and date the prescription in ink.

Q Can a prescriber's staff person call in or send a fax for a Schedule III – V prescription?

A Yes, however, the prescription must include the name of the person calling in or faxing the prescription. The pharmacist must reduce the prescription to hard copy form, record the staff person's name, and sign and date the prescription in ink.

LICENSED HEALTH CARE FACILITIES

Q Can a licensed skilled nursing facility, an intermediate care facility, a licensed home health program, or hospice care program call in or fax a Schedule II controlled substance order for a patient who is being discharged?

A No, the prescription would be an outpatient prescription and therefore must be written on the new tamper-resistant security prescription form or the triplicate form from July 1, 2004 to December 31, 2004 if the patient is being discharged. After January 1, 2005, it must be written on the new tamper-resistant prescription form.

Q What is an "institution" form for a qualified licensed health care facility?

A A *licensed health care facility* has the option of designating a prescriber to represent the health care facility. The designated prescriber's name, state license number, category of licensure, and DEA number are preprinted on the prescription form along with the facility name, address, state license number, and DEA number. The form also includes a blank space for the actual prescriber to handwrite, type, or stamp his or her name, state license number, category of licensure, and DEA number. The forms are delivered to the designated prescriber who is responsible for distributing the prescription forms to the other physicians in the facility. The designated prescriber must also maintain a record that includes the name, category of licensure, state license number, DEA number, and the quantity of forms issued to each prescriber and maintain the record in a readily retrievable format for 3 years. The designated prescriber may delegate any or all of these tasks to staff; however, the designated prescriber will be held accountable. The board recommends that the prescriber also record the batch/lot numbers of the forms distributed. (Health & Safety Code section 11162.1(c)(1) through (3).

Q Does my facility qualify as a "licensed health care facility" so that we can order "institution" prescription forms?

A "Licensed health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Health Services under Health and Safety Code section 1250. Clinics are authorized under Health and Safety Code section 1206 and are <u>not</u> eligible to use the institution form.

CALIFORNIA UTILIZATION, REVIEW, AND EVALUATION SYSTEM (CURES)

q What is CURES?

A The California Utilization, Review and Evaluation System (CURES) is a database that captures all Schedule II controlled substance prescriptions filled from data submitted by California pharmacies pursuant to Health and Safety Code section 11165. Beginning July 1, 2004, **dispensing** prescribers must submit data to CURES along with pharmacies. Effective January 1, 2005, pharmacies and **dispensing** prescribers must also submit Schedule III prescriptions to CURES.

Q How does a pharmacy submit data to the CURES system?

A Data must be submitted to CURES no later than the 18th of every month. Pharmacies must report electronically or via disk and must be accompanied by a completed CURES Program Transmittal form. Pharmacies must report even if they did not fill any Schedule II prescriptions; reported as zero on the CURES Program Transmittal form. Please contact the data collection vendor, Atlantic Associates, toll free at 1-888-492-7341 for more detailed information and data format specifications.

Q Do I need to enter the batch/lot number on the new tamper-resistant security prescription form into CURES?

A No, the batch/lot number is not tracked by the State. The batch number is not reported to the CURES system. Prescribers might consider using the batch number to track their forms internally for inventory purposes, and security printers might consider using the number to account for forms during the production process.

Q Can a physician have more than one DEA number?

A Yes. A physician who administers or dispenses controlled substances must have a separate DEA number for every address he or she practices. If the physician only writes prescriptions then he or she is only required to have one DEA number for all addresses.

Q I am a physician who dispenses controlled substance prescriptions to patients in my office. Do I need to report the information to the CURES system? If so, how do I report to CURES?

A On July 1, 2004, physicians must begin reporting all Schedule II controlled substances that are dispensed to patients from his or her office. As of January 1, 2005, all Schedule III controlled substances dispensed from a physician's office must also be reported to the CURES system. The Department of Justice, Bureau of Narcotic Enforcement, is in the process of developing a method for physicians to submit the data. For more information, please contact the Department of Justice, Bureau of Narcotic Enforcement at (916) 227-4051.

Q The new tamper-resistant security prescription forms are single copy forms, do I still need to report to CURES all Schedule II prescriptions filled?

A Yes, ALL pharmacies, hospitals, dispensing prescribers, or any other entity authorized to **dispense** Schedule II drugs are required to report to CURES electronically or via disk by the 18th of every month. Beginning January 1, 2005, both Schedule II and III must be reported to CURES. Please contact the Department of Justice, Bureau of Narcotic Enforcement, at (916) 227-4050 for information on how to submit data.

Q Our volume of Schedule II controlled substances dispensed is less than 25 per month and sometimes-even zero for a month; do I still need to report to CURES?

A Yes, currently all Schedule II prescriptions dispensed, and effective January 1, 2005 all Schedule III prescriptions dispensed, must be reported to CURES electronically or via diskette. You must also report any month that you did not fill any Schedule II or III prescriptions by marking zero under the "*Total number of prescriptions included"* on the CURES Program Transmittal Form. For more information or to obtain blank transmittal forms, please contact the data collection vendor, Atlantic Associates, at 1-888-492-7341, 7am to 7pm EST.

Q The new tamper-resistant security prescription forms are single copy forms; do I still need to report to CURES all Schedule II prescriptions filled?

A Yes, ALL pharmacies, hospitals, dispensing prescribers, etc authorized to **dispense** Schedule II drugs are required to report to CURES electronically or via disk by the 18th of every month. Beginning January 1, 2005, both Schedule II and III must be reported to CURES.

Q Does the pharmacy still send a copy of the Schedule II prescription to the Department of Justice?

A During the phase in period, July 1, 2004 through December 31, 2004, if you receive the Schedule II prescription on a triplicate form you are still required to send in the copy to the Department of Justice as well as report to CURES. If you receive the prescription on the new tamper-resistant security prescription form, you are only required to report to CURES.

Q What does a pharmacist enter into the triplicate number field in CURES when the prescription is written on the new tamper-resistant security prescription form?

A Between July 1,2004 and December 31, 2004, if the Schedule II prescription is written on a triplicate, enter the triplicate number. If it is written on the new tamper-resistant security prescription, enter all zeros or leave blank. After January 1, 2005, it will be on the new form so continue to enter all zeros or leave blank.

Agenda Item G

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: June 14, 2004**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **SB 1307 Update**

The Board of Pharmacy is sponsoring SB 1307 to strengthen the regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs. It was carefully developed to directly address issues found during its investigations of wholesale violations in California.

The bill has the following major elements:

- Requires the development of a "pedigree" that tracks each drug through the distribution system beginning January 1, 2007.
- Requires all out of state wholesalers shipping drugs into California to become licensed.
- Increases the board's ability to fine for more serious violations related to wholesaling.
- Requires wholesalers to post a $100,000 bond to secure administrative fines and penalties.
- Restricts wholesale transactions by pharmacies.
- Establishes "closed door pharmacies" as a type of pharmacy license.
- Requires that drugs be purchased only from licensed entities.
- Authorizes the board to embargo drugs when the board suspects or finds drugs that are adulterated or counterfeit.

As the bill moves through the Legislature, the board continues to work with all interested parties to resolve issues related to the bill.

Agenda Item H

Citation and Fine Statistics for July 1, 2003 – June 30, 2004

21 Office conferences were held this year

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Modified	Dismissed	Withdrawn
399*	302	197	43	72	82	23

*97 of these cases are scheduled for OC in June of 2004; their dispositions are not included

Average number of days from request to meeting date 21 days

- Total amount of fines issued FY 03/04 $939,259.00

Citation Breakdown by license type

Total Citations issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
1410*	303	21	345	273	285	41	52	4

* miscellaneous citations issued: 35 wholesalers, 18 exemptee's in charge, 3 vet distributors and drug rooms, 2 interns.

- Average number of days from date case opened until date citation is issued is 293. The current average is 142 days.

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	42	1716 - Variation from prescription	21	1716 - Variation from prescription	11
4051(a) - Conduct limited to a pharmacist; conduct authorized by pharmacist (unlicensed activity by a revoked pharmacist)	8	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	9	4125/1711 - Quality assurance program	11
1716/1761 - Variation from Rx / Erroneous Rx	7	4125/1711 - Quality assurance program	7	1714(b) - Operational standards and security; pharmacist responsible for pharmacy security	9
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	5	1716/1761 - Variation from Rx / Erroneous Rx	4	1715 - Self-assessment of a pharmacy by PIC	5
4125/1711 - Quality assurance program	4	1715 - Self-assessment of a pharmacy by PIC	3	1716.2 - Record requirements - compounding for future furnishing	4
4301(q) - Engaging in any conduct that subverts or attempts to subvert an investigation of the board.	3	4076 - Prescription container requirements for labeling	3	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	3
4063 – Refill of prescription for dangerous drug or device; Prescriber authorization.	3	4328 -Misdemeanor permitting compounding, dispensing, or furnishing by non-pharmacist	2	4115(e) - Pharmacy technician license required	3
4231/1732.5 - Requirements for renewal of pharmacist license/ Accreditation agencies	2	4116/1716(b) -Security of dangerous drugs & devices/Operational standards and security; pharmacy responsible for pharmacy security	2	1793.7(e) - Requirements for pharmacies employing pharmacy technician - Job description and written policies and procedures required	3
1707.2 – Duty to consult	2	1716.2 - Record requirements - compounding for future furnishing	2	1716/1761 - Variation from Rx / Erroneous Rx	3
1715 - Self-assessment of a pharmacy by the pharmacist in charge	2	4113(a)(c)/1709.1 - Pharmacist in charge notification to board and responsibilities /Designation of a pharmacist in charge	2	4116/1716(d) -Security of dangerous drugs & devices/Operational standards and security; pharmacist responsible for pharmacy security	2

Revision date 6/01/04

Fines Assessed
Statistic Comparison

Statistic Category	02/03	03/04
Total number of citations issued	908	1410
Average days from case open to citation	228	142
Total amount of fines assessed	$407,775.00	$939,259.00
Total amount of fines collected to date	$361,975.00	$852,707.00
Number of office conferences requested	124	399
Total number of conferences held	20	21
Average number of days from request to office conference	31	21
Total number of appearances	97	197
Number of citations dismissed	20	82
Number of citations modified	17	72
Number of citations affirmed	60	43